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Biotechnology

New Law Comes Into Force January 1, 2001

2000

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Report Highlights: The Czech government spent much of 2000 establishing a domestic regulatory framework for biotechnology. In May, Law 153/2000 on the 'use of genetically modified organisms' was adopted and recently the implementing decrees for this law were published. The law and the decrees come into force on January 1, 2001. They cover the contained use, deliberate release into the environment, and placing marketing of GMOs and products containing or consisting of GMOs. Consumer product labeling is not covered by this law. The full English text of the law and implementing decrees are attached to this report.

Includes PSD changes: No
Includes Trade Matrix: Nosdfg
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Background on Law No. 153/2000

The Czech Republic is a candidate for European Union (EU) membership and is in the process of harmonizing its laws with those of the EU. Law 153/2000 is based on EU rules on biotechnology and provides the basis for the implementation of EC Directive 90/219/EEC, as amended by Directive 98/81/EEC and EC Directive 90/220/EEC, including some new amendments and the Cartagena Protocol on Biosafety.

The responsible government authority on the use of GMOs and on biosafety is the Minsitry of Environment. It cooperates with the Minsitry of Health and the Ministry of Agriculture. The Law establishes a Commission for the Use of GMOs, which will act as an advisory body to the Ministry of Environment. The Commission is made up government officials, scientists, and representatives from non-government organizations (NGOs). The Commission will assess applications for GMO release or use. If approved, GMOs and products of GMOs will have to be registered. In comparison to existing EU rules, Law No. 153/2000 is in some respects more specific because it introduces lists: lists of users, lists for contained use, lists for the introduction of GMOs into the environment, and list for commercial use. All lists will be posted on the Ministry of Environment's webpage (www.env.cz).

The Law on GMO does not deal with the approval and labeling of food products. Labeling is dealt with under Law No. 110/97 on Foodstuffs and Tobacco Products, which was amended in 2000. This law calls for labeling beginning in 2002.

Summary of the Implementing Legislation

There are three Decrees (attached) that spell out how Law No. 153/2000 will be implemented. The first, Decree No. 372, is taken from EU Directives and defines what constitutes a GMO based on the technical procedures that are used to make the product. The second, Decree No. 373, lays down the requirements for containing GMOs and preventing unwanted environmental release. (Note: This decree was prepared based on draft EU legislation which has not yet been

adopted by the EU.) The third, Decree No. 374, defines "GMO users." Under the rules, an importer of genetically modified soybeans would be considered a user and the importers name would appear on the Ministry's website. Decree No. 374 also describes risk assessment procedures.

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[Following are English translations of Law No. 153/2000 and its three implementing decrees]

English Text of Law No. 153/2000

153

ACT

of 10 May 2000

on the use of genetically modified organisms and products and amendment of some related Acts

The Parliament has adopted the following Act of Law of the Czech Republic:

PART ONE

THE USE OF GENETICALLY MODIFIED ORGANISMS AND PRODUCTS

CHAPTER I

INTRODUCTORY PROVISIONS

 # 1
The Subject and the Scope of the Act

(1) The Act lays down the obligations of persons and the competence of the administrative authorities in the use of genetically modified organisms and products.

(2) If a genetically modified organism is a medicinal substance pursuant to the special legal regulation[1]), then it shall not be subject to the provisions of # 9 of this Act.

 # 2
Basic Definitions

For the purposes of this Act:

a) **organism** shall mean a biological entity, cellular or non-cellular, capable of replication or of transferring heritable genetic material, including viruses, viroids, animal and plant cells in a

[1]) Act No. 79/1997 Coll., on medicinal substances and supplementing some related Acts, as amended by Act No. 123/2000 Coll.

culture,

b) heritable genetic material shall mean deoxyribonucleic or ribonucleic acid,

c) genetic modification shall mean the intentional alteration of the heritable genetic material of an organism in a manner that cannot be achieved by natural recombination, that is the introduction of foreign heritable genetic material into the heritable genetic material of the organism or removal of part of the heritable genetic material of the organism,

d) genetically modified organism shall mean an organism, with the exception of human beings, whose heritable genetic material has been altered through genetic modification; technical procedures, that may result in the creation of a genetically modified organism and technical procedures that are not considered to result in creation of genetically modified organism, shall be laid down in a Decree,

e) product shall mean a preparation containing one or more genetically modified organisms, that was produced or obtained in any other way, regardless of the degree of processing thereof, and that is intended for placing on the market,

f) use of genetically modified organisms and products shall mean any activity involving genetically modified organisms or products from the formation thereof by genetic modification up to the instant when they lose the ability to replicate or transfer heritable genetic material,

g) user shall mean a legal person or natural person authorized to operate a business, who is authorised to use genetically modified organisms or products which have not been placed on the market pursuant to # 9, or who applies for this authorization,

h) contained space shall mean a space bounded by physical barriers, or by a combination of physical barriers with chemical or biological barriers, which limit the contact of genetically modified organisms and products with human beings, animals and the environment[2]),

i) contained use of genetically modified organisms shall mean the use of genetically modified organisms in a contained space, in particular the formation thereof by genetic modification, and the culture, storage and disposal thereof,

j) introduction of genetically modified organisms into the environment shall mean intentional release thereof into the environment outside the contained space, for any other purpose than placing on the market,

k) placing of genetically modified organisms and products on the market shall mean provision or offer of provision thereof in return for payment or free of charge to any other person for the purpose of distribution or use; this shall not apply to the procedure referred to in # 9 par. 2.,

l) risk assessment of the use of genetically modified organisms and products shall mean a

[2]) Act No. 17/1992 Coll., on the environment, as amended by Act No. 123/1998 Coll.

written analysis defining the risk represented by the assessed use of the genetically modified organism or product for the health of human beings and animals, the environment and biological diversity[3], carried out on the basis of verified scientific knowledge, experience and the principle of risk precaution,

m) risk category shall mean classification of the use of the genetically modified organism or product based on the risk assessment result of the activity, listed in Annex 1 to this Act,

n) accident shall mean any event during the use of genetically modified organisms or products involving a significant unintentional release of the genetically modified organisms, that can cause immediate or delayed hazard to the health of human beings and animals, the environment and biological diversity.

CHAPTER II
GENERAL PROVISIONS
3

(1) In the use of genetically modified organisms and products, every individual shall be obliged to protect the health of human beings and animals, the environment and biological diversity.

(2) Genetically modified organisms may be used in the following ways:
a) contained use of genetically modified organisms (hereinafter “contained use”),
b) introduction of genetically modified organisms into the environment (hereinafter “introduction into the environment”),
c) placing of genetically modified organisms and products on the market (hereinafter “placing on the market”.

(3) Authorization for the use of genetically modified organisms and products pursuant to this Act shall arise through a decision on registration in the pertinent list and terminate by a removal therefrom, except when this Act lays down otherwise (# 7 par. 4). These lists shall be:
a) The List of persons authorized for a certain manner of use of genetically modified organisms and products (hereinafter the "List of Users"),
b) The List of genetically modified organisms registered for contained use (hereinafter the “List for Contained Use”),
c) The List of genetically modified organisms registered for introduction into the environment (hereinafter the “List for Introduction into the Environment”),
d) The List of genetically modified organisms and products registered for the placing on the market in the Czech Republic (hereinafter the “List for the placing on the market”).

(4) An application for registration into the Lists set forth in par. 3 shall be submitted by the user to the Ministry of the Environment (hereinafter the "Ministry") in the Czech language in quadruplicate and simultaneously in electronic form.

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[3]) Communication of the Ministry of Foreign Affairs No. 134/1999 Coll. on negotiation of the Convention on Biological Diversity

(5) Immediately after receiving an application for the registration in the Lists set forth in paragraph 3, the Ministry shall forward one copy thereof each to the Ministry of Health, the Ministry of Agriculture and the Czech Commission for Use of Genetically Modified Organisms and Products (hereinafter the "Commission"). These Ministries and the Commission shall inform the Ministry in writing on their standpoints within 45 days of receiving the application. Having considered these standpoints, the Ministry shall issue a decision within 90 days of receiving the application. If the application is not complete, the Ministry shall request a complement thereof and shall suspend the administrative procedure[4]). If the administrative procedure is suspended, the period for the issue of the decision shall not proceed. The Ministry shall send the decision also to the Ministry of Health, to the Ministry of Agriculture and to the Commission. The Ministry may limit the period of validity of the consent and, in justified cases and on the basis of a request from the user, it may prolong the period of validity thereof.

(6) In the decision, the Ministry shall lay down conditions for the use which shall also follow from the standpoints of the Ministries and the Commission pursuant to paragraph 5.

(7) The user shall be obliged

a) to appoint a professionally qualified and blameless natural person to carry out expert control over the use of genetically modified organisms and products (hereinafter “professional consultant”); the requirements for the qualification shall be a completed university education in a relevant branch and at least 5 years experience in the branch, 2 years of which shall be in work with genetically modified organisms; details of the qualification requirements shall be laid down in a Decree,
b) to keep records of the use of genetically modified organisms and products for each workplace and to store these documents for a period of at least 10 years following the date of termination of the use of the genetically modified organism or product; the manner and scope of keeping records shall be laid down in a Decree,
c) to submit to the Ministry in written and electronic form, a list of the genetically modified organisms and products which he or she uses, and information on the amount and manner of use thereof for the past calendar year, by February 15 of each calendar year,
d) to send to the Ministry within 60 days from the termination of the use of the genetically modified organism or product, a report on the results of this activity, particularly in relation to any risk of hazard to the health of human beings and animals, the environment or biological diversity,
e) to provide for the carrying out of an assessment of the risks posed by the use of the genetically modified organisms and products (hereinafter a "risk assessment") pursuant to # 4 and to prepare an emergency response plan pursuant to # 5,
f) to provide for the code of practice of the workplace where the genetically modified organisms or products are used, to contain also the information listed in Annex 2 to this Act,
g) to provide for training of his or her employees prior to commencing the use of genetically modified organisms or products and for refresher courses following every change of work process or at least once a year, and to demonstrably acquaint the employees with the code of practice of the workplace,
h) to notify the Ministry, Ministry of Health and Ministry of Agriculture immediately, and at the latest within 24 hours after discovery, of every accident, by telephone, in written form or by

[4] # 29 of Act No. 71/1967 Coll., on administrative procedure (the Code of Administrative Procedure)

electronic mail, stating the genetically modified organisms or products involved, the amount thereof, the site where the accident occurred, the possible consequences of the accident, in particular the potential risks for the health of human beings and animals, the environment and biological diversity, and the means of elimination thereof,

i) to provide the Administrative authorities pursuant to # 14, # 17 to 19 with cooperation in inspection of the premises and facilities intended for the use of genetically modified organisms and products, to enable inspection of documents and, where applicable, to allow samples to be taken free-of-charge for test purposes,

j) to notify the Ministry of any change in information listed in the application pursuant to paragraph 4. The Ministry, following consultations with the Ministry of Health and Ministry of Agriculture and within 60 days after the notification, shall decide whether it is necessary to submit a new application for registration in the Lists set forth in paragraph 3. A new application must be submitted by the user within 30 days after this decision comes into force.

(8) Activities related to the use of live vertebrates, especially activities that intervene in their physiological functions or modify their metabolic products, shall be considered to constitute experiments on animals pursuant to the special regulations[5]).

(9) An application submitted pursuant to paragraph 4 must include the opinion of the professional consultant.

(10) If the genetically modified organism or product is registered according to # 7 to 9 in any of the lists mentioned in paragraph 3 let. b) to d), it shall not be necessary to submit a new application for registration therein.

 # 4
Risk Assessment

(1) The user shall be obliged to submit a risk assessment to the Ministry

a) as a part of the application for registration in the Lists set forth in # 3 par. 3,
b) regularly following the expiry of 5 years from the date of the last completed risk assessment,
c) within 20 days in cases set forth in # 6 par. 8.

Details and processes of the risk assessment shall be laid down in a Decree.

(2) The risk assessment must contain an evaluation of potential direct and indirect detrimental effects on the health of human beings and animals, the environment and biological diversity, both immediate and delayed, in particular an evaluation of

a) the adverse impact on human beings,
b) the adverse impact on fauna and flora,
c) compromising of the ability to treat a disease or to provide for effective prophylaxis resulting from resistance to antibiotics,
d) colonization and spreading of genetically modified organism in the environment,
e) natural transfer of inserted genetic material to other organisms.

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[5]) Act No. 246/1992 Coll., on protection of animals against cruelty, as amended.

(3) The user shall be obliged to provide for utilization in the risk assessment of
a) current scientific knowledge,
b) verified experience with the organism that is genetically modified and with related organisms,
c) verified experience with the organism that is the source of the heritable genetic material, if the genetic modification includes the use of such material,
d) verified experience with the genetic modification involved,
e) verified experience with the genetically modified organism or product involved,
f) qualified estimates in cases where verified scientific information is lacking; in these cases it shall be necessary to use the precautionary principle,
g) the opinion of the professional consultant.

(4) The user shall be obliged to provide for carrying out of a risk assessment for each genetically modified organism separately.

 # 5
The Emergency Response Plan

(1) The emergency response plan shall be a document describing activities and measures carried out in case of an accident, that lead to mitigation of the consequences thereof for the health of human beings and animals, for the environment and for biological diversity.

(2) The user shall be obliged to submit an emergency response plan to the Ministry
a) as a part of the application for registration in the Lists set forth in # 3 par. 3,
b) regularly following the expiry of 5 years from the date of the last submission of an emergency response plan,
c) within 30 days of a change in facts that could seriously affect measures laid down for the case of an accident.

(3) Prior to commencement of the use of genetically modified organisms and within 15 days of every subsequent submission pursuant to paragraph 2 letters b) and c), the user shall be obliged to provide the emergency response plan also to the Ministry of Health, to the Ministry of Agriculture, to the affected municipalities accordingly to the place of use and, where appropriate, to persons that could be affected by any accident.

(4) The emergency response plan must state all the information related to a potential hazard to the health of human beings and animals and damage to the environment and biological diversity as a consequence of an accident. The emergency response plan must contain in particular
a) the first name, surname, place of residence, telephone number and, where applicable also fax number and e-mail address of the professional consultant,
b) an exact description of the premises and facilities where the use of the genetically modified organisms and products takes place, where they are stored and where an accident could occur, stating the location of these premises,
c) methods and procedures that can be used for detection and inactivation of the genetically

modified organisms and products concerned in accordance with special legal regulations[6]),
d) methods and procedures for protection of health of human beings and animals, the environment and biological diversity,
e) the relevant administrative authorities mentioned in # 13 according to their competence and the means of notifying them, and the manner of warning the inhabitants, where appropriate,
f) opinion of the professional consultant.

The details of the emergency response plan shall be laid down in a Decree.

 # 6
Registration of the User

(1) An application for registration in the List of Users, submitted by a user to the Ministry prior to commencement of the use of a genetically modified organism or product, must contain:
a) the name, surname, state citizenship, place of residence, business address, identification and birth certificate numbers for a natural person authorized to operate a business,
b) the business name, legal form, business address and identification number of a legal person,
c) the name, surname, place of residence of the professional consultant, documents on his or her blamelessness, qualification and experience,
d) the officially verified copy of the business license in case of a natural person authorized to operate a business,
e) an excerpt from the Business Index, which shall not be more than 3 months old, or the officially verified copy of a charter, in case of a legal person,
f) the manner of use of the genetically modified organism or product,
g) the purpose and duration of the use of the genetically modified organism or product,
h) the address and description of the workplaces or properties at which the use will take place,
i) information on the organism that is genetically modified including the origin thereof,
j) information on the genetic modification, including information for identification of the altered heritable genetic material,
k) information on the genetically modified organism or product,
l) information on whether the given genetically modified organism has already been approved in any other country and for what purposes,
m) risk assessment pursuant to # 4, including a classification of the use of genetically modified organism or product in the risk category,
n) the emergency response plan pursuant to # 5,
o) a description of the use of the genetically modified organism or product in accordance with the risk assessment, including measures for protecting of the health of human beings and animals, the environment and biological diversity,
p) information on the system of carrying out tests and the means of inactivation of the genetically modified organisms in accordance with the special legal regulations[6)],
q) the treatment of waste, including hazardous waste, waste water and waste gaseous products in

[6]) E.g. Act No. 246/1992 Coll., on protection of animals against cruelty, as amended, Act No. 166/1999 Coll., on veterinary care and amending related Acts (the Veterinary Act), Act No. 125/1997 Coll., on waste, as amended by Act No. 167/1998 Coll.

accordance with the special legal regulations[7]).

(2) Professional qualification shall be proven by a certificate of completed university education in a relevant branch and by a document certifying the required experience pursuant to # 3 par. 7 letter a); blamelessness shall be proven by an extract from the Criminal Register which shall not be more than 3 months old, certifying that the person has not been convicted for premeditated criminal act. Further details of certain information contained in the application for each manner of use shall be laid down by a Decree.

(3) An applicant may submit a joint application for a particular manner of use in the same risk category with a combination of genetically modified organisms.

(4) The List of Users shall contain
a) identification information on the user mentioned in the application,
b) identification information on the professional consultant,
c) the address of the workplace where the use of the genetically modified organisms or product will take place,
d) specification of the genetically modified organism or product, or several organisms pursuant to paragraph 3,
e) the manner of use of the genetically modified organism or product,
f) the period of validity of the decision on registration, if stated.

(5) The user shall be removed from the List of Users on the basis of
a) expiry of the period of validity of the registration,
b) a decision of the Ministry on removal from the List of Users pursuant to paragraph 6 and 7,
c) the liquidation or extinguishment of a legal person or termination of the authorization to operate a business of a natural person,
d) the death of a natural person authorized to operate a business or the declaring dead thereof.
Removal from the List of Users shall not lead to termination of the obligations following from the decision on registration in the List of Users.

(6) If the user infringes against the provisions of this Act or fails to comply with the conditions laid down by the decision on registration in the List of Users, the Ministry shall make a decision on removal of such user from the List of Users. A new application for registration in the List of Users may be submitted at earliest five years from the date of a decision on removal from the List of Users.

(7) The Ministry may remove a user from the List of Users on the basis of a request thereby or if new facts occur that consequently change the conditions under which he/she was registered in the List of Users.

(8) If the Ministry obtains new information on possible hazards for the health of human beings and animals, the environment or biological diversity, resulting from the use of the genetically modified organism or product in question, either during the period of assessing of the application

[7]) E.g. Act No. 125/1997 Coll., on waste, as amended

or after the user has been registered in the List of Users, it shall ask the user to, at the latest within 20 days of receiving the request,

a) carry out a new risk assessment pursuant to # 4,
b) review the measures set forth in the application pursuant to paragraph 1 letter o) and, if appropriate, change them so as to ensure protection of the health of human beings and animals, the environment and biological diversity.

(9) The obligation to apply for registration in the List of Users shall not apply to Administrative Authorities mentioned in # 13, if they use genetically modified organisms within the extent of their competence as set forth in # 14 to 19 and to a legal person with whom the Ministry has concluded a contract on cooperation in execution of its competence pursuant to # 14.

 # 7
Contained Use

(1) A user may use genetically modified organisms only in a contained space that complies with the requirements on containment and protective measures laid down for the pertinent or higher risk category. If the risk assessment carried out pursuant to # 4 has not resulted in the definite assignment of the use of the genetically modified organism to a certain risk category, it is necessary to assess the use in compliance with the requirements for the higher risk category. Requirements on contained space and protective measures for the individual risk categories shall be laid down in a Decree.

(2) An application for registration in the List of Users in the case of contained use must contain the information set forth in # 6 par. 1 and furthermore

a) a description of the location of the premises for contained use and technical description of its facilities,
b) an assessment of this premises and facilities and their location pursuant to the requirements on contained space and protective measures laid down for the individual risk categories,
c) the expected amount of genetically modified organisms that are to be used.

Further details of certain information contained in the application shall be laid down by a Decree.

(3) If contained use in the first risk category, exclusively for the purposes of teaching or scientific research and development, is involved, the user shall enter in the application for registration in the List of Users, the organism or a group of organisms and genetic modifications that are to be used.

(4) In case of contained use in the first and second risk categories, the user may commence activities 90 days after submitting the application if the Ministry does not decide otherwise by the end of this period of time. In case of contained use in the third and fourth risk categories, the user may commence activities only with the consent of the Ministry.

(5) In case of contained use in the first and second risk categories, the Ministry shall register

the genetically modified organism mentioned in the application, or a group of organisms pursuant to paragraph 3, in the List for contained use, at the same time as it registers the user in the List of Users

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(6) In case of contained use in the third and fourth risk categories, the user shall be obliged, together with the application for registration in the List of Users, to submit an application for registration of the genetically modified organism in the List for contained use. The user may commence the contained use in the third and fourth risk categories only after the decision on registration of the genetically modified organism in the List for contained use has come into legal force.

(7) The application for registration of a genetically modified organism in the List for contained use must contain the information set forth in # 6 par. 1, paragraph 2 and also

a) information on the function of the genetic modification,
b) a description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid permitting unambiguous identification of the genetically modified organism.

Further details of certain information contained in the application shall be laid down by a Decree.

(8) The List for contained use shall contain

a) specification of the genetically modified organism, or a group of organisms pursuant to paragraph 3,
b) specification of the genetic modification,
c) the risk category,
d) identification of the user who uses this genetically modified organism,
e) the purpose of such use,
f) the period of validity of the decision on registration, if laid down.

(9) If the Ministry obtains new information that could mean a risk caused by the contained use under the set conditions, it shall, within 60 days of the date of obtaining such information, lay down by a decision for the user, new conditions of the contained use or conditions for suspension or termination of the contained use, including inactivation of the genetically modified organisms. The Ministry, after consulting the Ministry of Health and the Ministry of Agriculture, may, on the basis of new information, make a decision on a change in the risk category for contained use of a genetically modified organism registered in the List for contained use. In such a case, the user shall be obliged, within the period of time laid down in the decision, to ensure the premises and facilities correspond to the changed risk category and carry out the appropriate measures. If the user fails to do so within the set time period he/she must not proceed with the contained use.

(10) The user shall be obliged during the contained use to review the contained space and the protective measures regularly according to the code of practice and shall do so immediately in the case mentioned in # 6 par. 8 or when the Ministry has made a decision on a change of assignment to a risk category pursuant to paragraph 9.

 # 8
Introduction into the Environment

(1) Only a user registered in the List of Users may introduce genetically modified organisms into the environment, within the scope of his/her registration therein.

(2) Only genetically modified organisms that are registered in the List for introduction into the environment may be introduced into the environment, while maintaining all the conditions set forth in the decision on registration in this List.

(3) An application for registration of a genetically modified organism in the List for introduction into the environment must contain the information set forth in # 6 par. 1 and also

a) information on the function of the genetic modification,
b) description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid, permitting unambiguous identification of the genetically modified organism,
c) identification of the user or users who will carry out the introduction into the environment or participate therein, including documents or officially verified copies of the application for registration of such persons in the List of Users,
d) information on the sites at which the genetically modified organism will be introduced into the environment and the location thereof,
e) the amounts of genetically modified organisms that are to be used and the area over which the genetically modified organisms will be introduced into the environment,
f) measures that are intended to prevent the spreading of the genetically modified organisms during the introduction into the environment and the occurrence and spreading thereof at the given site after termination of the introduction into the environment,
g) information on possible interactions between the genetically modified organism and the environment.

Further details of certain information contained in the application shall be laid down by a Decree.

(4) If the introduction into the environment of several genetically modified organisms assigned to the first risk category is involved, that is carried out at the same time and for the same purpose, exclusively for the purposes of teaching or scientific research and development, the user may submit a single joint application.

(5) The List for introduction into the environment shall contain

a) specification of the genetically modified organism,
b) specification and the function of the genetic modification,
c) the result of the risk assessment,
d) identification of the user who shall use this genetically modified organism,
e) the purpose and site of introduction into the environment,
f) the period of validity of the decision on registration if laid down.

(6) If the Ministry obtains new information that could indicate a risk caused by introduction of the genetically modified organism into the environment under the set conditions, it shall, within 60 days of the date of obtaining such information, lay down by a decision for the user, new conditions for the introduction into the environment or the conditions for suspension or termination of the use.

(7) The Ministry after consulting the Ministry of Health and the Ministry of Agriculture may, on the basis of new information, decide to remove a genetically modified organism from the List for introduction into the environment. In the decision the Ministry shall lay down the conditions for the termination of the introduction of the genetically modified organism into the environment and the means of inactivation of the genetically modified organisms used. The Ministry shall publish the decision in the Bulletin of the Ministry and shall also send the decision to the Ministry of Health and Ministry of Agriculture.

 # 9
Placing on the Market

(1) Only genetically modified organisms and products registered in the List for placing on the market may be placed on the market, while maintaining all the conditions set forth in the decision on registration in this List. Decision-making on placing on the market thereof pursuant to the special legal regulations[8]) shall be in no way prejudiced by this provision.

(2) The provision of genetically modified organisms for scientific and testing purposes, for teaching and for collections shall not be considered to constitute placing on the market. Genetically modified organisms that are so provided must be clearly labelled "genetically modified organism" on the container.

(3) An application for registration of a genetically modified organism or product in the List for placing on the market must contain the information set forth in # 6 par. 1 and also

a) a document on registration of the user in the List of Users or an officially verified copy of an application for registration in this List,
b) information on the function of the genetic modification,
c) description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid, permitting unambiguous identification of the genetically modified organism,
d) the means of laboratory testing for the presence of the genetic modification,
e) information on whether the particular genetically modified organism is registered in the List for introduction into the environment,
f) information on whether the particular genetically modified organism or product has been approved for placing on the market in other countries and under what conditions,
g) specification of the product and the usage thereof,
h) the means of packaging and labelling in compliance with the special legal regulations[8]), including the proposed instructions for consumers,
i) information on possible interactions between the genetically modified organism or product and the environment,
j) provision, manner and scope of keeping records on the use of the genetically modified organism

[8]) E.g. Act No. 110/1997 Coll., on foodstuffs and tobacco products and amending and supplementing some related Acts, as amended, Act No. 91/1996 Coll., on feedingstuffs, Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, as amended, Act No. 147/1996, on plant medicinal care and amending some related Acts, Act No. 166/1999 Coll., on veterinary care and amending some related Acts (the Veterinary Act), Act No. 79/1997 Coll., on medicinal substances and supplementing some related Acts, as amended by Act No. 123/2000 Coll.

or product after it has been placed on the market, or the monitoring of the effects of the genetically modified organism or product on the health of human beings and animals, the environment and biological diversity, when appropriate; the provision for, manner and frequency of informing the Ministry.

Further details of certain information contained in the application shall be laid down by a Decree.

(4) The List for placing on the market shall contain

a) specification and the usage of the genetically modified organism or product,
b) specification and function of the genetic modification,
c) the conclusions of the risk assessment,
d) the means of laboratory testing for the presence of the genetic modification,
e) identification of the user who applied for registration of the genetically modified organism or product in this List,
f) the conditions laid down in the decision on registration of the genetically modified organism or product in the List for placing on the market,
g) the period of validity of the decision on registration if laid down.

(5) Every person who places a genetically modified organism or product on the market shall be obliged to

a) comply with all the conditions laid down in the decision on registration of the genetically modified organism or product in the List for placing on the market,
b) ensure that the labelling on the packing of the genetically modified organism or product clearly states in a visible place: "genetically modified organism", or "this product contains a genetically modified organism"; such labelling must also appear in the accompanying documents.

The special legal regulations laying down requirements concerning packaging and labelling of products[8)] shall be in no way prejudiced by this provision.

(6) If the Ministry obtains new information that could mean a risk caused by placing of the genetically modified organism or product on the market under the set conditions, it shall, within 60 days of the date of obtaining such information, lay down by a decision new conditions for placing on the market. The Ministry shall publish the decision in the Bulletin of the Ministry and shall also send the decision to the Ministry of Health and Ministry of Agriculture.

(7) The Ministry after consulting the Ministry of Health and the Ministry of Agriculture may, on the basis of new information, decide to remove the genetically modified organism or product from the List for placing on the market. The Ministry shall publish the decision in the Bulletin of the Ministry and shall also send the decision to the Ministry of Health and Ministry of Agriculture.

(8) A legal or physical person who uses the genetically modified organism or product registered in the List for placing on the market shall not be considered to be a user.

 # 10

Import, Export and Transit of Genetically Modified Organisms and Products

(1) Genetically modified organisms and products that have not been placed on the market in

the Czech Republic may be imported, exported or placed in transit only by a user registered in the List of Users, in the manner and within the scope of use of genetically modified organisms and products as set forth in the registration in the List of Users.

(2) Every person that imports, exports or places in transit a genetically modified organism or product, registered in the List for placing on the market pursuant to # 9, shall be obliged to provide for compliance with all the conditions laid down in the decision on the registration of the genetically modified organism or product in the List for placing on the market, and in particular its packaging and labelling.

(3) Imported and exported genetically modified organisms and products and genetically modified organisms and products in transit must have on the packing a visible label clearly stating "genetically modified organism" or "this product contains a genetically modified organism"; this text in the Czech language and in the language of the country of destination must also appear in the accompanying documents.

(4) The accompanying documents of imported or exported genetically modified organisms and products or genetically modified organisms and products in transit must, in case of a genetically modified organism or product that has not yet been registered for placing on the market in the Czech Republic, contain a copy of the decision on registration of the user in the List of Users and a copy of the decision on registration of the genetically modified organism in the List mentioned in # 3 paragraph 3 let. b) or c), an emergency response plan pursuant to # 5 and the result of risk assessment pursuant to # 4. If a genetically modified organism or product registered for placing on the market in the Czech Republic is involved, the accompanying documents must contain all the information mentioned in the registration in the List for placing on the market pursuant to # 9 par. 4.

(5) The special legal regulations laying down the conditions for import, export and transit[9]) shall be in no way prejudiced by the provisions of paragraphs 1 to 4.

 # 11
Business Secrecy *(Confidentiality)*

(1) In his/her applications, a user may indicate information, the disclosure of which could damage his/her competitive position, as being the subject of business secrecy pursuant to the special legal regulations[10]). Justification of this request must be verifiably demonstrated.

(2) The following must not be indicated as being the subject of business secrecy

a) specification of the genetically modified organism or product and the function of the genetic modification,

[9]) E.g. Act No. 21/1997 Coll., on control of the export and import of goods and technology subject to international control regimes, Act No. 42/1980 Coll., on economic contacts with foreign countries, as amended, Act No. 13/1993 Coll., the Customs Act, as amended, Act No. 166/1999 Coll., on veterinary care and amending some related Acts (the Veterinary Act) and Act No. 147/1996 Coll., on plant medicinal care and amending some related Acts.
[10]) E.g., Act No. 513/1991 Coll., the Commercial Code, as amended.

b) description of the genetic modification and of the part of the altered deoxyribonucleic or ribonucleic acid, permitting unambiguous identification of the genetically modified organism,
c) the business name and business address or name and place of residence of the user,
d) the site and reason for introduction into the environment or the purpose of placing on the market,
e) the risk assessment and measures to protect the health of human beings and animals, the environment and biological diversity,
f) methods and programs for monitoring the genetically modified organism or product following its introduction into the environment or placing on the market,
g) the emergency response plan,
h) evaluation of predictable undesirable effects and the means of protection against such effects.

(3) The obligation to maintain secrecy about facts indicated by the user as being the subject of business secrecy shall apply to all persons who assess the applications or carry out tests of the genetically modified organisms in accordance with # 6 par. 9. The obligation to maintain secrecy shall continue even if the application is rejected or withdrawn, for a period of 5 years from submission of the application.

 # 12
Informing the Public

(1) The Ministry shall enable every person to peruse the Lists mentioned in # 3 par. 3, to make excerpts, written extracts or copies thereof.

(2) Once a year the Ministry shall publish the up-dated Lists mentioned in # 3 par. 3 in the Bulletin of the Ministry as of December 31 of the previous calendar year.

(3) The right to information pursuant to the special legal regulations[11]) shall be in no way prejudiced by this Act.

(4) A civic association, whose purpose according to the Articles is protection of the environment or protection of the rights or interests of consumers, shall have the right to participate in an administrative procedure[12]) conducted pursuant to # 6 to 9 of this Act, provided it has requested the Ministry for participation therein.

(5) A request pursuant to paragraph 4 shall be valid for a period of one year from the date of submission thereof to the Ministry.

(6) The Ministry shall notify the civic association pursuant to paragraphs 4 and 5 of the commencing of a procedure at the same time as it notifies the participants in the procedure.

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[11]) Act No. 123/1998 Coll., on the right to information on the environment.
Act No. 106/1999 Coll., on the free access to information.
[12]) Act No. 71/1967 Coll., on administrative procedure (the Code of Administrative Procedure), as amended by Act No. 29/2000 Coll.

CHAPTER III
STATE ADMINISTRATION

 # 13
Administrative Authorities in the Sector
of the Use of Genetically Modified Organisms and Products

The competent administrative authorities for the sector of the use of genetically modified organisms and products shall be:

a) the Ministry of the Environment,
b) the Ministry of Health,
c) the Ministry of Agriculture,
d) the Czech Environmental Inspection (hereinafter the "Inspection"),
e) the customs authorities,
f) the bodies of the veterinary administration,
g) the Central Agricultural Control and Testing Institute,
h) the State Institute for Control of Pharmaceuticals,
i) the Institute for State Control of Veterinary Biopreparations and Pharmaceuticals,
j) the State Phytosanitary Administration,
k) the Czech Agricultural and Foodstuff Inspection.

 # 14
The Ministry

(1) The Ministry shall

a) be the central administrative authority in the area of assessing the impact of genetically modified organisms and products on the environment and biological diversity,
b) execute supreme state supervision in the area of the use of genetically modified organisms and products from the standpoint of protection of the environment and biological diversity,
c) lay down procedures for risk assessment in the use of genetically modified organisms and products pursuant to # 4 from the standpoint of protection of the environment,
d) establish the Commission as its administrative part,
e) make decisions pursuant to # 3 par. 5 on registration in the Lists mentioned in # 3 par. 3 and on removal from the Lists pursuant to # 6 par. 5 to 7, # 8 par. 7 and # 9 par. 7,
f) keep the Lists mentioned in # 3 par. 3,
g) make information available to the public pursuant to # 12,
h) execute the function of the competent administrative authority for international exchange of information in the area of genetically modified organisms,
i) be the appeal body against decisions of the Inspection.

(2) The Ministry shall authorize the Commission to

a) follow scientific and technical developments in the area of the use of genetically modified organisms and products and, when necessary, inform the Ministry and recommend appropriate measures,

b) control the information set forth in applications pursuant to # 3, # 6 to 9 and issue standpoints on these applications pursuant to # 3 par. 5,
c) carry out professional inspections of the workplaces of users and sites of introduction into the environment in cooperation with administrative authorities mentioned in # 17 and 19,
d) carry out professional inspections of documents kept by the users pursuant to # 3 par. 7 let. b) in cooperation with administrative authorities mentioned in # 17 and 19,
e) discuss the reports prepared by users pursuant to # 3 par. 7 let. d),
f) propose methods for testing of genetically modified organisms and propose equipment of workplaces for carrying out such tests.

(3) The Minister of Environment shall name and recall the chair and members of the Commission, after consulting the Ministers of Health and Agriculture, from amongst professionals nominated by the administrative authorities mentioned in # 13, by the Academy of Sciences of the Czech Republic and by civic associations. In carrying out of the activities mentioned in paragraph 2, the Commission shall be subject to the statute and the rules of procedure, which shall be issued by the Ministry.

 # 15
The Ministry of Health

The Ministry of Health shall
a) propose to the Ministry procedures for assessment of health risks connected with the use of genetically modified organisms and products,
b) issue standpoints from the aspect of protection of human health to the applications pursuant to # 3 par. 5.

 # 16
The Ministry of Agriculture

The Ministry of Agriculture shall
a) propose to the Ministry procedures for assessment of risks connected with the use of genetically modified organisms and products from the standpoint of agriculture,
b) issue standpoints to the applications pursuant to # 3 par. 5.

 # 17
The Inspection

(1) The Inspection shall
a) control how legal persons and natural persons comply with the provisions of the legal regulations and with the conditions laid down by the decisions of the Ministry related to the use of

genetically modified organisms and products, from the standpoint of the environment, and cooperate with the customs authorities;
b) impose on legal persons and natural persons remedial measures and penalties for infringement against obligations pursuant to this Act,
c) carry out inspections on its own or in cooperation with the administrative authorities mentioned in # 14, # 18 and 19.

(2) Inspectors of the inspection shall be entitled to enter the properties and premises to the absolutely necessary extent, to carry out inspection pursuant to paragraph 1. In this, they must provide authorization to carry out the inspection. The state shall be liable for any damage caused by the inspection; it may not relieve itself of this liability.

 # 18
The Customs Authorities

The customs authorities shall
a) control consignments that are declared as genetically modified organisms or products at border crossing points, to ensure that they are accompanied by the appropriate documents pursuant to # 10 of this Act and the special legal regulations for transit[13]), export and import[9]),
b) impound the goods, in case of discovery of any infringement against this Act or in case of suspicion thereof, inform the Inspection and the Ministry thereof and, in case of doubt, ask the Inspection for professional assistance,
c) keep records of all consignments of genetically modified organisms and products allowed to cross the border and enable the employees of the Ministry and Inspection to peruse such records, make excerpts therefrom, copy information or make copies thereof, including providing this evidence in electronic form or by e-mail.

 # 19
Other Administrative Bodies

(1) The bodies of the veterinary administration, the State Phytosanitary Administration, the Czech Agricultural and Foodstuff Inspection, the Central Agricultural Control and Testing Institute, the State Institute for Control of Pharmaceuticals and the Institute for State Control of Veterinary Biopreparations and Pharmaceuticals
a) shall carry out state professional control of the use of genetically modified organisms and products, and control and tests of genetically modified organisms and products within the framework of their jurisdictions and pursuant to special legal regulations[14]),

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[13]) Decree of the Ministry of Foreign Affairs No. 64/1987 Coll., on the European Agreement on international highway transport of dangerous goods (ADR) as amended by Communication of the Ministry of Foreign Affairs No. 159/1997 Coll. and Communication of the Ministry of Foreign Affairs No. 54/1999 Coll., Act No. 111/1994 Coll., on highway transport, as amended by Act No. 38/1995 Coll. and Act No. 304/1997 Coll.
[14]) E.g. Act No. 166/1999 Coll., on veterinary care and amending some related Acts (the Veterinary Act), Act No. 147/1996 Coll., on plant medicinal care and amending some related Acts, Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, as amended.

b) in cases of discovery of infringement against this Act, shall submit to the Inspection a proposal for commencement of an administrative procedure and shall immediately inform the Ministry thereof.

(2) The special legal regulations[14)] shall be in no way prejudiced by the provisions of paragraph 1.

(3) Supervision of protection of the health of employees at workplaces where genetically modified organisms are used, carried out by the bodies of the hygiene service, shall be the subject of special legal regulations[15]).

 # 20
Remedial Measures

(1) The Inspection may require that persons, who use genetically modified organisms or products without authorization or contrary to this Act, carry out, at their own cost, remedial measures consisting, for example, in preventing the release of the genetically modified organism from the contained space, in preventing the occurrence or spread of the genetically modified organism or product in the environment or in the immediate inactivation of the genetically modified organism or product.

(2) If the person causing the impediments pursuant to paragraph 1 is not found or there could be a hazard following from delay, the above measures may also be imposed by the Inspection on the owner of the property on which or in which the use of the genetically modified organisms or products occurs or, as appropriate, the Inspection may carry out these measures itself. If the Inspection carried out the remedial measure itself for reasons of hazards associated with delay, the costs connected with the remedial measure shall be paid by the person causing the impediment or by the owner of the property.

 # 21
Penalties

(1) The Inspection shall impose a penalty of 100 000 to 1 000 000 CZK on a person who
a) fails to comply with the general conditions for the use of genetically modified organisms and products pursuant to # 3,
b) fails to comply with obligations related to risk assessment pursuant to # 4,
c) does not have or does not comply with the emergency response plan pursuant to # 5,
d) states untrue information when keeping records pursuant to # 3 par. 7 let. b),
e) fails to comply with the requirements for placing genetically modified organisms or products on the market pursuant to # 9,
f) fails to comply with the conditions related to import, export and transit pursuant to # 10.
g) fails to comply with remedial measures pursuant to # 20,

[15]) Act No. 20/1966 Coll., on the health of the population, as amended.

h) fails to comply with obligations laid down in # 11.

(2) The Inspection shall impose a penalty of 700 000 to 1 500 000 CZK on a user who
a) fails to comply with the conditions in the decision on the use of genetically modified organisms or products, laid down pursuant to # 3,
b) uses genetically modified organisms or products contrary to the information set forth in the List of Users pursuant to # 6,
c) fails to comply with the conditions for contained use pursuant to # 7,
d) fails to comply with the conditions for introduction into the environment pursuant to # 8.

(3) In making a decision on the amount of a penalty, the Inspection shall take into consideration particularly the seriousness of the infringement against obligations, the duration of the illegal state and the detrimental consequences of the illegal acts that have occurred or of which there is a hazard.

(4) If repeated infringement against the obligations, for which a fine was imposed pursuant to paragraphs 1 and 2, occurs within a period of 1 year of the date of legal force of the decision on imposing of the fine, and the user has not complied with the measures for a remedy laid down by the Inspection within the set period of time, the Inspection shall impose a fine on such person up to an amount of twice the sum laid down in paragraphs 1 and 2.

(5) An administrative procedure on imposing a penalty may be commenced within 2 years of the date when the Inspection discovered the infringement against obligations and at the latest 5 years from the date when the infringement against obligations occurred.

(6) The imposing of a penalty pursuant to paragraphs 1 and 2 shall in no way prejudice liability pursuant to the special legal regulations[16]).

(7) Penalties shall be collected and levied by the Inspection, which shall proceed pursuant to the special legal regulation[17]).

(8) A penalty shall be due within 30 days of the date of legal force of the decision by which the penalty was imposed and shall be an income for the State Environmental Fund of the Czech Republic.

 # 22
Relation to the Code of Administrative Procedure

(1) Decision-making pursuant to this Act shall be subject to the Code of Administrative Procedure[12)] unless stated otherwise in this Act.

(2) Appeals against a decision on imposing remedial measures pursuant to # 20 shall not have

[16]) Act No. 40/1964 Coll., the Civil Code, as amended.
[17]) Act No. 337/1992 Coll., on administration of taxes and fees, as amended.

dilatory effect.

CHAPTER IV
TEMPORARY AND CONCLUDING PROVISIONS

 # 23

(1) Persons using genetically modified organisms prior to the date when this Act comes into effect shall be obliged to submit an application for registration in the List of Users pursuant to # 6 at the latest within 120 days of the date when this Act comes into effect.

(2) Persons carrying out contained use of genetically modified organisms in the third and fourth risk categories, according to the conclusion of the risk assessment submitted with the application pursuant to paragraph 1, shall be obliged to submit an application for registration of the genetically modified organisms that they use in the List for contained use pursuant to # 7 par. 5, at the latest 120 days from the date when this Act comes into effect.

(3) Persons who introduce genetically modified organisms into the environment on the basis of a consent issued by the Ministry prior to the date when this Act comes into effect, shall be obliged to submit an application for registration of these genetically modified organisms in the List of genetically modified organisms approved for introduction into the environment pursuant to # 8 at the latest six months from the date when this Act comes into effect.

 # 24

The Ministry, in agreement with the Ministry of Health and the Ministry of Agriculture, shall lay down by a Decree

a) technical procedures, that may result in the creation of a genetically modified organism and technical procedures that are not considered to result in creation of genetically modified organism [# 2 let. d)],
b) details of the qualification requirements for the professional consultant [# 3 par. 7 let. a)],
c) manner and scope of keeping records [# 3 par. 7 let. b)],
d) details and procedures for the risk assessment (# 4),
e) details of the emergency response plan (# 5),
f) further details of certain information contained in the application for registration into the List of Users for each manner of use (# 6 par. 1, # 7 par. 2),
g) requirements on contained space and protective measures for the individual risk categories in contained use (# 7 par. 1),
h) further details of certain information contained in the application for registration into the List for contained use (# 7 par. 5),
i) further details of certain information contained in the application for registration into the List for introduction in the environment (# 8 par. 3),
j) further details of certain information contained in the application for registration into the List for placing on the market (# 9 par. 3).

PART TWO
AMENDMENT OF THE ACT ON ADMINISTRATIVE CHARGES

 # 25

In Act No. 368/1992 Coll., on administrative charges, as amended by the Act No. 10/1993 Coll., Act No. 72/1994 Coll., Act No. 85/1994 Coll., Act No. 273/1994 Coll., Act No. 36/1995 Coll., Act No. 118/1995 Coll., Act No. 160/1995 Coll., Act No. 301/1995 Coll., Act No. 151/1997 Coll. and Act No. 305/1997 Coll., Act No. 149/1998 Coll., Act No. 157/1998 Coll., Act No. 167/1998 Coll., Act No. 63/1999 Coll., Act No. 166/1999 Coll., Act No. 223/1999 Coll., Act No. 326/1999 Coll., Act No. 352/1999 Coll., Act No. 357/1999 Coll., Act No. 360/1999 Coll., Act No. 363/1999 Coll., Act No. 46/2000 Coll., Act No. 62/2000 Coll., Act No. 117/2000 Coll., Act No. 133/2000 Coll., Act No. 151/2000 Coll., Act No. 154/2000 Coll., Act No. 156/2000 Coll., Act No. 158/2000 Coll., shall be amended as follows:

In the rate lists of administrative charges, following item 131b, a new item 131c shall be inserted, that shall read:

"**Item 131c**

a) for issuing of a decision on registration in the List of persons authorized for a certain manner of use of genetically modified organisms and products 10 000 CZK
b) for issuing of a decision on registration in the List of genetically modified organisms approved for contained use 2 000 CZK
c) for issuing of a decision on registration in the List of genetically modified organisms approved for introduction into the environment 20 000 CZK
d) for issuing of a decision on registration in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic 30 000 CZK

PART THREE
AMENDMENT OF THE ACT ON VARIETIES, SEEDS AND SEEDLINGS OF CULTIVATED PLANTS

 # 26

Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, as amended by the Act No. 357/1999 Coll., shall be amended as follows:

1. In # 2, letter c) shall read:

"c) a genetically modified plant shall mean a plant that is a genetically modified organism[1a)],".

Footnote No. 1a shall read:

"[1a)] # 2 of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

2. In # 2 a new letter d) shall be inserted after letter c) that shall read

"d) genetically modified variety shall mean a variety that includes genetically modified plants,"

The existing letters d) to m) shall be designated as letters e) to m).

3. In # 6 par 3, letter b) shall read:

"b) if a genetically modified variety is involved, prove that the genetically modified plants are registered in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation[4a]),".

Footnote No. 4a) shall read:

"[4a] # 3 par. 3 letter d) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

4. In # 7 at the end of let. f) the period shall be replaced by a comma and new letter g) shall be added, that shall read:

"g) if it includes genetically modified plants, these shall be registered in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation[4a]).".

5. In # 12 at the end of par. 1, the period shall be replaced by a comma and new letter i) shall be added, that shall read:

"i) information on the function of the genetic modification[4b].".

Footnote No. 4b shall read:

"[4b] # 2 letter c) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

6. In # 16 at the end of par. 1, the period shall be replaced by a comma and new letter i) shall be added, that shall read:

"h) if a variety includes genetically modified plants that were removed from the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation[4c].".

Footnote No. 4c) shall read:

"[4c] # 9 par 9 of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

7. In # 16 par. 2 the words "letter e)" shall be replaced by the words "let. e) and h)".

8. In # 28, par. 2 shall read:

"(2) Information on the packaging of propagation material placed on the market and required by this Act must be

a) readily legible and indelible,
b) if propagation material of a genetically modified variety is involved, it must contain labelling pursuant to the special legal regulation[7a].".

Footnote No. 7a shall read:

"[7a] # 9 par. 5 of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

9. In # 26 new paragraphs 3 and 4 shall be added that, including footnotes No. 11) and 12), shall read:

"(3) The administrative procedure on registration of a variety pursuant to # 5 ff., commenced before the legal force of the special regulation[11], concerning the registration of a variety including genetically modified plants, shall be suspended until it is proven that these genetically modified plants have been registered in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special regulation[12].

(4) An applicant who, prior to the legal force of the special regulation[11], has proven in an administrative procedure on the registration of a variety, that the Ministry of the Environment consents pursuant to # 6 par. 3 let. b) to the field growing of a variety that includes genetically modified plants, shall be obliged, within 30 days of the legal force of the special regulation[11], to apply for the registration of these plants in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special regulation[12]. If the Ministry of Environment decides that it will not register such a plant in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special regulation[12], the administrative procedure shall be terminated.

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[11] Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.

[12] # 9 par. 5 of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts.".

PART FOUR
AMENDMENT OF THE ACT ON MEDICINAL SUBSTANCES

27

Act No. 79/1997 Coll., on medicinal substances and amending and supplementing some related Acts, as amended by the Act No. 149/2000 Coll., shall be amended as follows:

1. In # 25 new paragraph 9 shall be added that shall read:

"(9) If a medicinal preparation containing a genetically modified organism is involved, the State Institute for Control of Pharmaceuticals for a human medicinal substance or the Institute for State Control of Veterinary Biopreparations and Pharmaceuticals for a veterinary medicinal substance shall request the standpoint of the Ministry of the Environment on assessment of the risk for the environment pursuant to the special legal regulation*). The Ministry of the Environment shall

issue this standpoint within a period of 90 days. It may decide not to issue this standpoint in cases where this standpoint was submitted together with the application or the application was submitted together with a report on environmental impact assessment carried out by a competent authority in the European Union.”.

Footnote No. 17a shall read:
“[17a)] Act No. 153/2000 Coll., on use of genetically modified organisms and products and amending some related Acts.".

2. In # 35 par. 1 letter a) at the end of the text, the following words shall be added:

"and if a human medicinal substance is involved, that contains genetically modified organisms that have not been contained yet in any human medicinal preparation that is already registered, such a permit may be issued only if the genetically modified organism is registered in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic pursuant to the special legal regulation [19a)].”.

Footnote No. 19a shall read
“[19a)] # 9 of Act No. 153/2000 Coll., on use of genetically modified organisms and products and amending some related Acts.".

3. In # 39 paragraph 1 at the end of letter a), the following words shall be added:

" if a veterinary medicinal substance is involved, that contains genetically modified organisms that have not been yet contained in any veterinary medicinal preparation that is already registered, such a permit may be issued only if the genetically modified organism is registered in the List of genetically modified organisms and products approved for placing on the market in the Czech Republic pursuant to the special legal regulation [19a)].”.

PART FIVE
EFFECT

28

This Act shall come into effect on January 1, 2001.

Annex No. 1 to Act No. 153/2000 Coll.

Risk Categories

The result of assessment of the risk resulting from the use of a certain genetically modified organism or product shall be an assignment of this activity to one of the following risk categories:

A) The first category shall include activities with no or minimal risk of detrimental impact on the health of human beings and animals, the environment or biological diversity.

B) The second category shall include activities with a risk of such detrimental impact on the health of human beings and animals, the environment or biological diversity that can be easily eliminated by generally known measures.

C) The third category shall include activities with a risk of such detrimental impact on the health of human beings and animals, the environment or biological diversity that can be eliminated only by especially demanding interventions.

D) The fourth category shall include activities with a risk of such detrimental impact on the health of human beings and animals, the environment or biological diversity that has a permanent impact and cannot be completely eliminated even by especially demanding interventions.

Annex No. 2 to Act No. 153/2000 Coll.

The details of the Code of Practice of the workplace where the genetically modified organisms or products are used

The Code of Practice of the workplace where the genetically modified organisms or products are used must contain:

a) identification information on the user pursuant to # 6 par. 1 let. a) and b) of the Act,
b) identification information on the owner of the premises or property, if the owner is not identical with the user,
c) the first name, surname, place of residence, telephone number and, where applicable, also fax number and e-mail address of the professional consultant,
d) the risk category of the use of the genetically modified organism, that may be carried out at the workplace,
e) the person or persons responsible for the operation of the workplace,
f) characterization, the use and description of the technical installations providing for the containment, if contained use is involved,
g) a list and description of the standard operating procedures used at the workplace,
h) a list of personnel trained for work at the workplace,
i) a list of genetically modified organisms or products that shall be used at the workplace and the approximate amounts thereof,
j) organizational and technical provisions for the workplace,
k) measures for the case of fire or accident, including the emergency response plan pursuant to # 5,
l) the duties of personnel at work (adherence to standard operational principles, the procedures of sanitation of the facilities after the end of work, the procedures of decontamination of the instruments, personal protective aids and clothing),
m) the system and frequency of reviewing the premises, installations and protective measures,
n) duties of the personnel in maintenance of the equipment,
o) principles of safety and hygiene at work pursuant to the requirements of the special legal regulations[15],
p) management of waste and contaminated materials and equipment, especially the processes of inactivation of genetically modified organisms and testing for the effectiveness thereof,
q) a list of obligatory equipment and personal safety means, stating the activities where these means must be employed,
r) activities prohibited at the workplace,
s) principles of keeping records on the operation of the facilities, on sanitation carried out and reviews of protective installations,
t) means to restrict access of unauthorised persons,
u) the date and issue number of the registration in the List of Users,
v) information on the limit of validity of the Code of Practice, if applicable.

The Code of Practice must contain an officially verified number of pages; it shall be prohibited to remove or damage the individual pages thereof. The Code of Practice must be kept pursuant to # 3 par. 7 let. b).

English Text of Implementing Decree 372

372

Decree
of
the Ministry of the Environment

of October 6, 2000

laying down the technical procedures, that may result in a genetically modified organism and technical procedures that are not considered to result in a genetically modified organism

Pursuant to § 24 letter a) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related acts, the Ministry of the Environment, in agreement with the Ministry of Health and the Ministry of Agriculture, hereby lays down:

§ 1

Genetically modified organisms may be yielded using

w) the technique of recombinant nucleic acids forming new combinations of genetic material by the insertion of a section of nucleic acid prepared by whatever means outside of an organism into any virus, bacterial plasmid or other vector system and its subsequent incorporation into the organism of a recipient in which it does not normally occur but in which it is capable of further multiplication,
x) the technique of introduction of genetic material prepared by whatever means outside of an organism directly into the organism of the recipient, including micro-injection, macro-injection, biolistic methods, micro-encapsulation and artificial chromosomes, or
y) the technique of cell fusion (including protoplast fusion) or cell hybridization, in which fusion of two or several cells leads to the formation of a viable cell with a new combination of heritable material, by means of methods or means that do not occur naturally.

§ 2

(1) The following technical procedures may not result in a genetically modified organisms, on condition they do not involve the use of recombinant heritable material (deoxyribonucleic acid or ribonucleic acid) or genetically modified organisms formed using the techniques set forth in § 1:

a) in vitro fertilization,
b) bacterial conjugation, transformation, transduction and similar natural processes,
c) induction of polyploidism and haploidism,
d) mutagenesis, or
e) crossing.

(2) For the purposes of the contained use, the following technical procedures may also not result in a genetically modified organism, on condition they do not involve the use of recombinant

heritable material (deoxyribonucleic acid or ribonucleic acid) or genetically modified organisms formed using the techniques set forth in § 1:

a) fusion of cells or protoplasts of procaryontic organisms, that can exchange genetic material by a known physiological process, or
b) fusion of cells or protoplasts of eucaryontic organisms, including formation of hybridomas and fusion of plant cells.

(3) For the purpose of introduction into the environment, a technique of fusion of plant cells or protoplasts may also not result in a genetically modified organism if the resultant organism can also be obtained by traditional breeding methods, on condition this technique does not involve the use of recombinant genetic material (deoxyribonucleic acid or ribonucleic acid) or genetically modified organisms formed using the techniques set forth in § 1.

§ 3

This Decree shall come into effect on January 1, 2001.

Minister:
Dr. Kužvart

English Text of Implementing Decree 373

373
Decree
of
the Ministry of the Environment

of October 6, 2000

laying down the requirements on contained space and protective measures for the individual risk categories in contained use of genetically modified organisms

Pursuant to § 24 letter g) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related acts (hereinafter "the Act"), the Ministry of the Environment, in agreement with the Ministry of Health and the Ministry of Agriculture, hereby lays down:

§ 1

(1) The requirements on contained space and protective measures for contained use of genetically modified organisms (hereinafter "contained use") are set forth in Annexes Nos. 1 to 4 according to the type of workplace and risk category. Assignment of the use of a genetically modified organism or product to one of the risk categories [§ 2 letter m) of the Act] shall be the result of risk assessment [§ 2 letter l) of the Act] carried out pursuant to § 4 of the Act and § 4 of the Decree on detailed conditions for the use of genetically modified organisms and products[18]).

(2) The space and equipment corresponding to any higher risk category may be also used for contained use in a particular risk category.

(3) Compliance with the Code of Practice of the workplace and provisions for training and instruction of personnel shall also constitute part of the protective measures.

(4) The provisions of paragraphs 1 to 3 shall in no way prejudice the special legal regulations[19].

§ 2

This Decree shall come into effect on January 1, 2001.

[18]) Decree No. 374./2000, on detailed conditions for the use of genetically modified organisms and products.
[19]) E.g., Decree No. 230/1999 Coll., laying down proper clinical practice and detailed conditions for clinical evaluation of medicinal substances, Decree No. 74/1998 Coll., laying down proper laboratory practice in the area of medicinal substances, Decree No. 311/1997 Coll., on the breeding and use of experimental animals.

Annex No. 1 to the Decree No. 373/2000 Coll.

Requirements on contained space and protective measures for microbiological laboratories

		For risk category			
		A (for the first category)	**B** (for the second category)	**C** (for the third category)	**D** (for the fourth category)
	Contained space				
1	Isolation inside of the building or location in a separate building	not required	isolation inside the building	isolation inside the building	location in a special building required
2	Sealable for fumigation	not required	not required	required	required
	Equipment				
3	Easily cleanable surfaces resistant to water, acids, alkalis, solvents; permiting effective disinfection and decontamination	required for the bench, floor and walls	required for the bench, floor and walls	required for the bench, floor and walls	required for the bench, floor, walls and ceiling
4	Entrance into the working area via airlock[1)]	not required	required only if this follows from the risk assessment	required	required
5	Decreased pressure relative to the pressure in the immediate surroundings	not required	not required	required	required
6	Extract and input of air through an aerosol filter (HEPA)	not required	not required	required for exit	required; where work is carried out with viruses, special measures against disseminati on of viruses required
7	Sterile box - separate room	not required	required only if this follows from the	required	required

			risk assessment		
8	Autoclave	required, in the building	required, in the building and conditions ad [2] must be fulfilled	required, in the contained space	required, in the laboratory; it must be inserted between the "clean" and "unclean" space
	System of work				
9	Limited access	not required	required	required	required
10	Sign "biological hazard" at the entrance	not required	required	required	required
11	Special measures for limiting spread of aerosols	not required	required to minimize spread	required to prevent spread	required to prevent spread
12	Shower	not required	required in the building	required	required
13	Protective clothing	suitable working clothing required	suitable protective clothing required; protective footwear required only if this follows from the risk assessment	suitable protective clothing and protective footwear required	suitable protective clothing, footwear and glasses required, with complete change of underwear, clothing and footwear prior to entering and leaving the contained space
14	Protective gloves	required only if this follows from the risk assessment	required	required	required
15	Effective control and	required	required	required	required

	prevention of vectors of genetically modified organisms (e.g. insects and rodents)				
	Wastes				
16	Inactivation of genetically modified organisms in effluent from washbasins, sinks, showers and in other waste waters	required only if this follows from the risk assessment	required	required	required
17	Inactivation of genetically modified organisms on used material and solid wastes in accord with the special legal regulations[3]	required	required, including disinfecting of protective clothing	required, including disinfecting of protective clothing and footwear and other protective aids	required, including disinfecting of protective clothing and footwear and other protective aids
	Other measures				
18	The laboratory has its own equipment	required	required	required	required
19	An observation window or other equipment is installed so that the workers in the laboratory can be seen	required only if this follows from the risk assessment	required only if this follows from the risk assessment	required	required
20	Resting room outside of the work area	not required	required only if this follows from the risk assessment	required	required

Footnotes:

[1] An airlock means the entrance to the laboratory through separated spaces. Their "clean" side shall be separated from the laboratory by safety doors, a changing room for changing clothing and by a shower.

[2] A standard operational procedure shall be followed, permitting safe transfer of material to the autoclave outside the laboratory and ensuring the same level of protection.

[3] E.g., Act No. 125/1997 Coll., on wastes, as amended.

Annex No. 2 to the Decree No. 373/2000 Coll.

Requirements on contained space and protective measures for glasshouses and growth-rooms

A glasshouse or growth-room means a contained space enclosed by walls, a floor and roof (ceiling), that is intended and predominantly used for cultivating plants. If other genetically modified organisms than plants are used in a glasshouse, the glasshouse must comply with the conditions laid down by this Decree for the appropriate workplace (e.g. Annex No. 1 for genetically modified microorganisms, Annex No. 3 for genetically modified animals).

Glasshouses and growth-rooms must comply with the following requirements:

		For risk category			
		A (for the first category)	**B** (for the second category)	**C** (for the third category)	**D** (for the fourth category)
	Contained space				
1	The glasshouse or growth-room is resistant to weather extremes in the given region	not required	required	required	required
2	Isolation inside the building or located in a separate building	not required	required only if this follows from the risk assessment	required only if this follows from the risk assessment	location in a special building required
3	Sealable for fumigation	not required	not required	required	required
	Equipment				
4	Entrance into the work area through a separate room with two interlocking doors	not required	required	entrance via an airlock[1] required	entrance through an airlock[1] required
5	Decreased pressure relative to the pressure in the immediate surroundings	not required	not required	required	required
6	Extract and input of air through an aerosol filter (HEPA)	not required	not required	required for exit	required
7	Autoclave	required, in the premises	required, in the building	required, in the building and conditions ad[2] must be fulfilled	required, in the contained space; it must be inserted

					between the "clean" and "unclean" space
	System of work				
8	Limited access	not required	required	required	required
9	Sign "biological hazard" at the entrance	not required	required	required	required
10	Shower	not required	required in the building	required	required
11	Protective clothing	suitable protective clothing required	suitable protective clothing required; protective footwear required only if this follows from the risk assessment	suitable protective clothing and protective footwear required	suitable protective clothing, footwear required, with complete change of clothing and footwear prior to entering and leaving the contained space
12	Protective gloves	required only if this follows from the risk assessment	required	required	required
	Wastes				
13	Inactivation of genetically modified organisms in the effluent from washbasins, sinks, showers and other waste waters in accord with the special regulations[3]	required only if this follows from the risk assessment	required	required	required
14	Inactivation of genetically modified organisms on used material and solid wastes in accord with the special regulations[3]	required	required, including of protective clothing	required, including protective clothing and footwear and other	required, including protective clothing and footwear

				aids	and other aids
	Other measures				
15	Limiting the occurrence of undesirable animals, insects, rodents, etc. by preventing access and regular treatment of the space and equipment with effective means	required	required	prevention of occurrence required	prevention of occurrence required
16	The glasshouse or growth-room has its own equipment	required	required	required	required
17	Water outflow only into an outlet that undergoes inactivation pursuant to point 13	required only if this follows from the risk assessment	required control of outflow outside the outlet	prevention of outflow outside the outlet required	prevention of outflow outside the outlet required
18	Treatment of waste soil in an autoclave or hot-air sterilizer	not required	required only if this follows from the risk assessment	required	required
19	The procedure of transferring organisms to other equipment must permit control over dissemination of genetically modified organisms	dissemination outside to the space to which it is relocated must be limited to the smallest possible degree	prevention of dissemination outside to the space to which it is relocated is required	prevention of dissemination outside to the space to which it is relocated is required	prevention of dissemination outside to the space to which it is relocated is required
20	Resting room	not required	required only if this follows from the risk assessment	required	required

Footnotes:

[1] An airlock means entrance to the glasshouse or growth-room through separated spaces. Their "clean" side shall be separated from the laboratory by safety doors, a changing room for changing clothing and a shower.

[2] A standard operational procedure shall be followed, permitting safe transfer of material to the autoclave outside the glasshouse or growth-room and ensuring the same level of protection as in these spaces.

[3] E.g., Act No. 125/1997 Coll., on wastes, as amended.

Annex No. 3 to the Decree No. 373/2000 Coll.

Requirements on contained space and protective measures for animal units

If genetically modified microorganisms are used in animal units, these spaces must simultaneously comply with the conditions specified by Annex No. 1 to this Decree. If clinical evaluation of human or veterinary medicinal substances containing genetically modified organisms is involved, the requirements on contained spaces and protective measures in accord with the special regulations shall be applied (e.g. Act No. 79/1997 Coll., on medicinal substances and amending and supplementing some related acts, as amended by Act No. 149/2000 Coll., Decree No. 230/1999 Coll., laying down proper clinical practice and the detailed conditions for clinical evaluation of medicinal substances).

In addition to the requirements following from the special legal regulations (e.g. Act No. 246/1992 Coll., on protection of animals against cruelty, as amended, Decree No. 311/1997 Coll., on the breeding and use of experimental animals, Law No. 166/1999 Coll., on veterinary care and amending related acts, the Veterinary Act, Act No. 20/1966 Coll., on care for the health of the population, as amended), the user installation for animals must also comply with the following requirements:

		For risk category			
		A (for the first category)	**B** (for the second category)	**C** (for the third category)	**D** (for the fourth category)
	Contained space				
1	The animal unit[1] is a separate unit	required only if this follows from the risk assessment	required	required	required
2	Animal facilities[2] are separated by lockable doors	required only if this follows from the risk assessment	required	required	required
3	Animal facilities and auxiliary facilities are designed so that they can be easily cleaned and decontaminated (material impermeable for water, easily washed and disinfected)	required	required	required	required
4	The floor and walls of the	required	required for	required for	required for

	chambers are easily washable	only if this follows from the risk assessment	the floor	the floor and walls	the floor and walls
5	The animals are kept in suitable containment facilities, such as boxes, pens or tanks	required	required	required	required
6	Filters on isolators[3] or isolated rooms	not required	required only if this follows from the risk assessment	required	required
7	In case of the use of products of animal origin provisions for control thereof (e.g. veterinary hygienic control)	required	required	required	required
In case of animal units for water animals					
8	Inactivation of the animals in waste waters	required	required	required	required
9	Design of the space preventing, in case of breakage, leaks or overflow of the vessels for the water animals, outflow into the sewers, surface or ground waters	required for escape of organisms	required for escape of organisms	required for leakage of water	required for leakage of water

Footnotes:

[1] Animal unit means a separate building or space inside a building containing facilities for animals and other auxiliary spaces (e.g. storehouse for feedingstuff, bedding and other aids), including the facilities for the personnel (e.g. changing rooms, showers, sterilizers, spaces for storing foodstuffs, etc.).

[2] Animal facility means installations and equipment, specialized according to the kind of animals for their housing and carrying out experimental procedures.

[3] An isolator means a transparent box in which small animals are kept; isolated rooms are preferable for larger animals.

Annex No. 1 to the Decree No. 373/2000 Coll.

Requirements on containment and other protective measures for other activities (e.g. for production operations, pilot plants)

		For risk category			
		A (for the first category)	**B** (for the second category)	**C** (for the third category)	**D** (for the fourth category)
	Contained system				
1	Viable organisms must be maintained in a contained system[1], which is separated from the surroundings	required only if this follows from the risk assessment	required	required	required
2	Safeguarding and regulation of spread of aerosols leaving the contained system	not required	limitation of dissemination to a minimum required	prevention of dissemination required	prevention of dissemination required
3	Safeguarding and regulation of spread of aerosols during taking samples or adding material to the contained system or transfer of material to another system	required only if this follows from the risk assessment	limitation of dissemination to the lowest possible degree required	prevention of dissemination required	prevention of dissemination required
4	Inactivation of the cultivation medium (fluids) prior to removal from the contained system	inactivation by a physical or chemical method necessary	inactivation by a physical or chemical method necessary	inactivation by a physical or chemical method with proven 100% efficiency necessary	inactivation by a physical or chemical method with proven 100% efficiency necessary
5	Design of the sealing and closings preventing dissemination of the organisms from the contained system	limitation of dissemination to the lowest possible degree required	complete prevention of dissemination required	complete prevention of dissemination required	complete prevention of dissemination required
	Other requirements on the				

	contained space				
6	The capture tank of the cultivation installation must contain the entire volume of the contained system if spillage occurs	required only if this follows from the risk assessment	required	required	required
7	Sealing for fumigation	not required	required only if this follows from the risk assessment	required only if this follows from the risk assessment	required
8	Entrance through a airlock[2]	not required	not required	required only if this follows from the risk assessment	required
9	Easily cleanable surface resistant to water, acids, alkalies, solvents, permits effective disinfection and decontamination	required for the working surface, floor and walls	required for the working surface, floor and walls	required for the working surface, floor and walls	required for the working surface, floors, walls and ceiling
10	Special ventilation equipment intended to limit contamination of the air to a minimum	required only if this follows from the risk assessment	required only if this follows from the risk assessment	required	required
11	Maintaining decreased pressure relative to the pressure in the immediate surroundings	not required	not required	required	required
12	Extract and input of air through an HEPA filter	not required	not required	required for exit; required for entrance only if this follows from the risk assessment	required for entrance and exit
	System of work				
13	The entire contained system	not required	required	required	required

	is located in a contained space		only if this follows from the risk assessment		
14	Limited access	required	required	required	required
15	Sign "biological hazard" at the entrance	not required	required	required	required
16	Personnel must shower prior to leaving the contained space	not required	not required	required	required
17	Protective clothing	working clothing required	working clothing required; working footwear required only if this follows from the risk assessment	protective clothing and protective footwear required	protective clothing and footwear required, with complete exchange of underwear, clothing and footwear prior to entering and leaving the contained space
	Wastes				
18	Inactivation of genetically modified organisms in the effluent from washbasins, sinks, showers etc.	required only if this follows from the risk assessment	required	required	required
19	Disinfection of protective clothing, footwear and individual protective aids after use	required only if this follows from the risk assessment	required	required	required
20	Inactivation of genetically modified organisms on the used material and in liquid and solid wastes during the	inactivation by a physical or chemical	inactivation by a physical or chemical	inactivation by a physical or chemical	inactivation by a physical or chemical

	process in accord with the special legal regulations[3]	method necessary	method necessary	method with proven 100% efficiency necessary	method with proven 100% efficiency necessary
	Other measures				
21	Resting room	not required	required only if this follows from the risk assessment	required	required

Footnotes

[1] A contained system means an installation permanently located in a contained space intended for the storage and cultivation of genetically modified organisms, usually in large volumes.

[2] An airlock means entrance to the contained space through separated spaces. Their "clean" side shall be separated from the contained space by safety doors, a changing room for changing clothing and a shower.

[3] E.g., Act No. 125/1997 Coll., on wastes, as amended.

English Text of Implementing Decree 374

374

DECREE
of
the Ministry of the Environment

of October 6, 2000

on detailed conditions for the use of genetically modified organisms and products

Pursuant to § 24 letters b) to f) and h) to j) of Act No. 153/2000 Coll., on the use of genetically modified organisms and products and amending some related Acts (hereinafter the "Act"), the Ministry of the Environment, in agreement with the Ministry of Health and the Ministry of Agriculture hereby lays down the detailed conditions for:

§1

For the purposes of this Decree:

c) a recipient means an organism into whose heritable material the foreign heritable material is inserted by genetic modification,
d) the donor organism means the organism from whose heritable material is derived the heritable material inserted into the genetic material of the recipient,
e) the parental organism means the organism from whose heritable material a part has been removed by genetic modification,
f) a vector means a noncellular entity containing heritable material and capable of incorporating this heritable material together with the inserted foreign heritable material into the cells of the recipient,
g) an insert means foreign heritable material inserted into the heritable material of the recipient,
h) a construct means an artificially modified molecule of nucleic acid,
i) a signal gene means a gene contained in the construct and rendering a easily determinable property of the cells or organism containing a functional construct,
j) a selection gene means a gene contained in a construct and rendering the lack of sensitivity to a certain substance or to an influence preventing the multiplication of cells that do not contain this gene,
k) a stage means the period of time during which an activity or a set of activities is carried out in the use of the genetically modified organism or product, directed towards a certain conclusion, obtaining of information or some other partial result,
l) primary data means all the laboratory and work records and documents or authenticated copies thereof that are the result of original observations, measurements and registrations of parameters.

§ 2
Detailed Conditions of the Professional Qualification of the Professional Consultant
(ad § 3 par. 7 letter a) of the Act)

(1) A condition for designating a natural person as a professional consultant shall consist in

properly completed university education[20]) in the field of
a) medicine, veterinary medicine, biochemistry or microbiology, for the use of genetically modified microorganisms,
b) the natural sciences, agriculture or forestry for the use of genetically modified plants, or
c) the natural sciences, agriculture or veterinary medicine for the use of genetically modified animals.

(2) The period of postgraduate or doctoral studies in the appropriate field and in the field of the use of genetically modified organisms shall be included in the period of the required two years of experience in the use of genetically modified organisms[21]).

(3) In supervision of an experiment using animals and other use of genetically modified animals, the professional consultant pursuant to paragraph 1 must also fulfill the conditions of qualification pursuant to the special legal regulations[22]).

§3
Details of the Applications for Entry in the Lists
(Ad §6 par. 1, §7 par. 2 and 7, §8 par. 3, and §9 par. 3 of the Act)

(1) As part of an application for entry in the lists specified in §3 par. 3 of the Act, the user may also submit the requested information on the properties of a genetically modified organism prepared for some other legal person or natural person licensed to operate a business, provided that (s)he simultaneously submits an authenticated identical copy of the consent of such person to the use of the submitted information by the user.

(2) Documents for the application required by this Decree, that are translations from foreign languages, shall be submitted in the form of an officially authenticated translation and simultaneously in the original. With the application, the user may enclose further information material in English language, together with a brief summary thereof in Czech.

(3) A sample application for entry in the List of Users for contained use of genetically modified organisms (hereinafter "contained use") is given in Annex No. 1; a sample application for entry in the List of Users for introduction of genetically modified organisms into the environment (hereinafter "introduction into the environment") is given in Annex No. 2; a sample application for entry in the List of Users for placing genetically modified organisms and products on the market (hereinafter "placing on the market") is given in Annex No. 3.

(4) If the application for entry in the List of Users is submitted pursuant to § 6 par. 3 of the Act, all the information for each genetically modified organism must be entered separately in the

[20]) Act No. 111/1998 Coll., on higher institutes of learning and amending and supplementing some other acts (the Act on higher institutes of learning).
[21]) §3 par. 7 letter a) of Act No. 153/2000 Coll., on the use of genetically modified organisms and amending some related acts.
[22]) §17 of Act No. 246/1992 Coll., on protection of animals against cruelty, as amended.

application; this shall not apply to the case set forth in § 7 par. 3 of the Act.

(5) A sample application for entry of a genetically modified organism in the List of genetically modified organisms registered for contained use is given in Annex No. 4.

(6) Samples of applications for entry of a genetically modified organism into the List of genetically modified organisms registered for introduction into the environment are given
a) in Annex No. 5, when the genetically modified organism is a microorganism,
b) in Annex No. 6, when the genetically modified organism is a higher plant, or
c) in Annex No. 7, when the genetically modified organism is an animal.

(7) If an application for entry in the List of genetically modified organisms registered for introduction into the environment is submitted pursuant to § 8 par. 4 of the Act, it is necessary to state in the application all the information separately for each genetically modified organism.

(8) Samples of applications for entry of a genetically modified organism or product into the List of genetically modified organisms and products registered for placing on the market in the Czech Republic are given
a) in Annex No. 8, when the genetically modified organism is an organism other than a higher plant, or
b) in Annex No. 9, when the genetically modified organism is a higher plant.

§ 4
Risk Assessment
(Ad § 4 of the Act)

(1) The purpose of risk assessment carried out according to § 4 of the Act shall be to identify and evaluate potential adverse effects of the proposed use of the genetically modified organism or product on the health of humans and animals, the environment and biological diversity. Risk assessment must take into consideration all the potential harmful effects, regardless of the likelihood of their occurrence, and compare them with the harmful effects of use of the recipient or parental organism or related organisms, as appropriate.

(2) The effects of the use of a genetically modified organism or product may be
a) direct, i.e. primary effects on the health of humans and animals, the environment and biological diversity, that are directly connected with the genetically modified organism or product,
b) indirect, i.e. effects on the health of humans and animals, the environment and biological diversity, that occur through a causal chain of events, e.g. through interaction with other organisms, transfer of heritable material or changes in the manner of use; indirect effects may be manifested with a delay,
c) immediate, i.e. effects that are observed during the use of the genetically modified organism or product; immediate effects may be direct or indirect,
d) delayed, i.e. effects that need not be observed during the use of the genetically modified organism or product but can be determined as direct or indirect effects after the termination of the use of the genetically modified organism or product.

(3) Potential harmful effects include
a) adverse effects on humans, including diseases, allergic and toxic effects,
b) adverse effects on animals and plants, including diseases, toxic or allergic effects,
c) influence on the population dynamics of species within the receiving environment and on the genetic diversity of each of these populations,
d) compromising prophylactic and therapeutic treatments in the area of medicine, veterinary medicine or plant medicine, e.g. through transfer of genes increasing the pathogenicity, virulence or toxogenicity of organisms or genes conferring resistance to antibiotics used in medicine or veterinary medicine,
e) effects on biogeochemical processes, particularly the carbon and nitrogen cycles, through changes in the decomposition of organic material in the soil.

(4) Harmful effects on the health of humans and animals, the environment and biological diversity may occur through
a) settlement and spread of genetically modified organisms in the environment,
b) natural transfer of inserted heritable material to other organisms,
c) phenotypic and genetic instability,
d) interactions with other organisms,
e) changes in the management of organisms or products, including changes in agrotechnical procedures.

(5) In risk assessment, it is necessary to identify the occurrence of potential harmful effects of the use of the genetically modified organism or product in connection with
a) the recipient,
b) the inserted heritable material (originally from the donor organism),
c) the vector,
d) the donor organism (if a donor organism is used in carrying out the genetic modification),
e) insertion of a construct,
f) the signal and selection genes,
g) the insert,
h) removal of a part of the heritable material (if used in the genetic modification),
i) the final genetically modified organism,
j) the location and scope of the use of the genetically modified organism or product,
k) the environment at the site of use,
l) potential interaction between the genetically modified organism or product and the environment at the site of use.

(6) The risk assessment must contain evaluation of the seriousness of every potential harmful effect and the likelihood of occurrence of this harmful effect, in the evaluated manner of use at the given workplace or site of introduction into the environment and under the conditions under which they are to be used or that could occur. The risk assessment must further take into consideration the characteristics of the activity and the danger following therefrom.

(7) The procedure in risk assessment shall consist in
a) identification of all potential harmful effects pursuant to paragraphs 2 to 5 and assessment of the

seriousness thereof,
b) evaluation of the consequences of each harmful effect, in case it occurs,
c) evaluation of the likelihood of occurrence of the harmful effect under the given conditions,
d) estimation of the risk for the health of humans and animals, the environment and biological diversity represented by each of the identified harmful effects on the basis of evaluation of the likelihood of occurrence of the harmful effect and the seriousness of this effect if it occurs,
e) comparison of the information obtained with the corresponding information for the donor organism, the recipient, and/or the parental organism under comparable conditions,
f) classification of the activity in the appropriate risk category pursuant to Annex No. 1 to the Act on the basis of the results obtained.

(8) All the steps in the procedure pursuant to paragraph 7 must be documented in writing and, where possible, documented by reference to the scientific literature, protocols from experimental studies or documentation on previous use. This written analysis must be stored together with the other documentation pursuant to § 3 par. 7 letter b) of the Act.

(9) The risk assessment must promptly reviewed if there is a change in
a) the scientific or technical knowledge related to the effects of use of the genetically modified organism or product pursuant to paragraphs 1 to 6, or
b) the procedure of the use of the genetically modified organism or product.

(10) The risk assessment for contained use must take into consideration the facts pursuant to paragraphs 1 to 6 and also
a) the characteristics of the environment that could be affected by dissemination of the genetically modified organism from the contained space,
b) the nature and scale of the contained use,
c) any nonstandard operations carried out during the contained use.
These facts may affect the classification of the use of the genetically modified organism in the pertinent risk category pursuant to paragraph 7) letter f).

(11) The risk assessment for introduction into the environment for genetically modified organisms other than higher plants must contain
a) the likelihood that, under the conditions of introduction into the environment, the genetically modified organism will become more persistent or more invasive than the recipient or parental organism in its natural habitat,
b) any selective advantage or disadvantage resulting from the genetic modification and the likelihood that this advantage or disadvantage will become realized under the conditions of introduction into the environment,
c) the possibility of transfer of the heritable material to other species under the conditions of introduction into the environment and each selective advantage or disadvantage that could be thus transferred,
d) the potential immediate or delayed effects on the environment caused by direct or indirect interactions between the genetically modified organism and the target organism (if a target organism exists),
e) the potential immediate or delayed environmental impact caused by direct or indirect interactions between the genetically modified organism and nontarget organisms, including the effect on the

population levels of competitors, prey, symbionts, predators, parasites and pathogens,

f) the potential immediate or delayed effects on human health resulting from potential direct or indirect interactions between the genetically modified organism and persons coming into contact therewith,

g) the potential immediate or delayed effects on the health of animals and consequences for food chains resulting from the consumption of the genetically modified organism or product, which is intended for use as a feedingstuff,

h) the potential immediate or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the genetically modified organism and target and nontarget organisms in the vicinity of the release of the genetically modified organism into the environment, and

i) the potential immediate or delayed, direct and indirect effects on the environment as a consequence of the use of specific techniques for the use of genetically modified organisms if these techniques differ from those normally used.

(12) The risk assessment for the release of genetically modified higher plants into the environment or for placing on the market, if the genetically modified higher plants are placed on the market as seeds or seedlings[23]), as appropriate, must contain the following resultant information:

a) the likelihood that, under the conditions of introduction into the environment, the genetically modified higher plants become more persistant than the recipient or parental organism in an agricultural environment or more invasive in the natural environment,

b) any selective advantage or disadvantage resulting from the genetic modification,

c) the potential of transfer of the heritable material to the same or a sexually compatible species under the conditions of cultivation of genetically modified higher plants and each selective advantage or disadvantage that can be thus transferred,

d) the potential immediate or delayed environmental impact resulting from direct or indirect interactions between the genetically modified higher plant and the target organism (if a target organism exists),

e) the potential immediate or delayed environmental impact resulting from direct or indirect interactions between the genetically modified higher plant and nontarget organisms, including the impact on the population level of competitors, herbivores, or symbionts, parasites and pathogens,

f) the potential immediate or delayed effects on human health resulting from potential direct or indirect interactions between the genetically modified higher plant and persons coming into contact therewith,

g) the potential immediate or delayed effects on the health of animals and the consequences for food chains resulting from consumption of a genetically modified higher plant or product, intended as a feedingstuff,

h) the potential immediate or delayed effects on biogeochemical processes following from potential direct and indirect interactions of the genetically modified higher plant and target and nontarget organisms in the vicinity of the place of cultivation of the genetically modified higher plant, and

i) the potential immediate or delayed direct and indirect environmental impacts as a consequence of the use of specific growing, harvesting and processing techniques for the genetically modified plants if these techniques differ from those in common use.

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[23]) Act No. 92/1996 Coll., on varieties, seeds and seedlings of cultivated plants, as amended.

(13) The risk assessment for a product containing several different genetically modified organisms must contain evaluation of the relevant information for each of these organisms.

§ 5
Emergency Response Plan
(ad § 5 letter of the Act)

An emergency response plan shall contain

a) the name, surname, place of residence, state citizenship, place of business, birth certificate number or date of birth, as appropriate, and also the identification number of the user pursuant to § 2 letter g) of the Act, in case of a natural person licensed to operate a business,
b) the name (business name), legal form, registered office and identification of the user pursuant to § 2 letter g) of the Act, and the name, surname and place of residence of the statutory body of the user, in case of a legal person,
c) the name, surname, place of residence, telephone number and fax number, as appropriate, and e-mail address of the professional consultant,
d) persons responsible for liquidation of accidents, the means of communication therewith and the organizational provisions for the case of occurrence of an accident,
e) an exact description of the property[24]), or premises and facilities where the use of the genetically modified organisms or products takes place, where they are stored and where an accident may occur, stating the place (address) where these properties or space are located; for export, import or transit, a description of the route,
f) a plan of the workplace, denoting places important for controling the consequences of an accident (the main control of the power source and sources of auxiliary media, sites of storage of the genetically modified organisms or products, safety features of the containment, for contained use, etc.); for export, import or transit, a description of preventing the dissemination of the genetically modified organisms or products,
g) a description of an accident that could occur in the facility or at the site where the genetically modified organisms and products are used,
h) a survey of potential consequences of an accident on the health of humans, animals and the environment and biological diversity, including the manner of determining these consequences and effective protection against them,
i) procedures for detection of the presence of the genetically modified organisms or products,
j) methods and procedures that can be used for inactivation of the genetically modified organisms or products involved and for decontamination of the areas affected,
k) methods for isolation of areas and equipment affected by the accident, including methods for controlling the effectiveness of the isolation,
l) description and depiction of the location of decontamination aids that can be used for inactivation of the genetically modified organisms or products involved and decontamination of the area affected,
m) procedures for protection of the health of humans and animals and protection of the environment

[24]) § 5 par. 1 of Act No. 344/1992 Coll., on the Land Register of the Czech Republic (the Cadastral Act), as amended.

in case of the occurrence of an undesirable effect caused by an accident; as appropriate, methods of disposal or sanitation of plants or animals located in the area during the accident, in accord with the special regulations[25]),

n) municipalities or persons, as appropriate, to whom the emergency response plan is submitted pursuant to § 5 par. 3 of the Act, and

o) the administrative authorities set forth in § 13 of the Act and the means of informing them in case of an accident, and the means of informing the inhabitants, as appropriate, in relation to the site of the accident and the potential consequences thereof.

§ 6
Keeping of the Documentation
(Ad § 3 par. 7 letter b) of the Act)

(1) Documentation on the use of genetically modified organisms and products (hereinafter "documentation") pursuant to § 3 par. 7 letter b) of the Act shall be

a) a copy of the application submitted pursuant to § 3 par. 4 of the Act,
b) the decision pursuant to § 3 par. 5 of the Act or an officially authenticated copy thereof,
c) assessment of the risk of the use of the genetically modified organism or product pursuant to § 4 of the Act,
d) evaluation of the space and the facilities pursuant to § 7 par. 2 letter b) of the Act for contained use of genetically modified organisms,
e) the code of practice of the workplace,
f) the emergency response plan prepared pursuant to §5 of the Act,
g) the operations day-books for the individual stages,
h) the final reports for the individual stages,
i) records of the controls carried out pursuant to § 7 par. 10 of the Act, for contained use of genetically modified organisms and
j) the final report pursuant to § 3 par. 7 letter d) of the Act.

(2) Documentation shall be drawn up, kept and stored in written and electronic form so that documents cannot be lost, damaged or stolen and so as to ensure that they are well-arranged and readily accessible if required. Access to the documentation must be limited only to persons appointed by the user or by the administrative authorities pursuant to § 3 par. 7 letter i) of the Act, as appropriate.

(3) Before commencing a stage, a plan of the stage shall be prepared, which shall contain

a) the purpose of the use of the genetically modified organism or product,
b) information on the genetically modified organism,
c) designation of the stage and its target,

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[25]) E.g., Act No. 353/1999 Coll., on prevention of serious accidents caused by selected dangerous chemical substances and chemical preparations and amending Act No. 425/1990 Coll., on District Authorities, outlining of their jurisdiction and some other related measures, as amended (the Act on prevention of serious accidents), Act No. 246/1992 Coll., on protection of animals against cruelty, as amended, Act No. 166/1999 Coll., on veterinary care and amending related Acts (the Veterinary Act), Act No. 125/1997 Coll., on wastes, as amended by Act No. 167/1998 Coll., Act No. 147/1996 Coll., on plant medicinal care and amending some related Acts.

d) the name, surname and address of the leader of the stage,
e) the name, surname and address of the professional consultant,
f) the address of the workplace and/or the position and a description of the property, as appropriate, where the stage will take place,
g) the date of commencing and the expected completion of the stage,
h) a list of the organisms to be used during the stage,
i) a list of the isolated heritable material to be used during the stage,
j) potential risks in the stage, including risks in case of an accident,
k) the category of risk of use of the genetically modified organism during the stage,
l) the procedure for use of the genetically modified organisms and products during the stage, including binding operational procedures to be used during the stage,
m) the monitoring system, in particular the methods of identification and monitoring of the genetically modified organism or product and its potential effects on the health of humans and animals, the environment and biological diversity,
n) the kind and amount of wastes formed during the stage and the management thereof in accord with the special regulations[26]),
o) the manner of further use of the genetically modified organism or product after completion of the stage in connection with the next stage, or the manner of disposal of the genetically modified organism or product and subsequent control of the effectiveness of the disposal, and
p) the statement of the professional consultant on the plan for the stage.

(4) The operations day-book, to be kept during the stage, shall contain
a) the plan of the stage,
b) a description of the progress of the stage, in particular every deviation of the progress of the stage from the plan for the stage,
c) primary data obtained during the stage,
d) records of all completed inspections and controls, and
e) records of all extraordinary events and accidents.

(5) If a change occurs during the stage in the information specified in paragraph 3, it shall be necessary to state the reasons for the change and the date when a decision was made on the change or when it occurred. The professional consultant shall confirm in the documentation that (s)he was notified of the change. In case of an intentional change, the professional consultant shall also confirm favorable evaluation of this change in the documentation,

(6) The person who records the data must do the recording promptly, exactly and legibly. In the record, (s)he must state his(her) name, surname and the date of the entry. Any change in the primary data shall be entered so that the original entry is legible. If necessary, the reason for the change must be affixed, along with the name and surname of the person who made the change, and the date and time of making the change, as appropriate.

(7) Information stored in electronic form shall be backed up. Changes and corrections to this information shall be stored separately. Records on photo-sensitive paper or other materials with limited lifetime must be transferred to a permanent record.

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[26]) E.g., Act No. 125/1997 Coll., on wastes, as appropriate.

(8) The documentation for a stage shall be completed by a final report that is favorably evaluated by the professional consultant. The final report shall contain in particular

a) the purpose of the use of the genetically modified organism or product,
b) designation of the stage and its target,
c) the name, surname and address of the leader of the stage,
d) the name, surname and address of the professional consultant,
e) the address of the workplace and/or the position and a description of the property, as appropriate, where the stage occurred,
f) the date of commencing and completing the stage,
g) information on the genetically modified organism used during the stage,
h) the isolated heritable material used during the stage, and the means of genetic modification, as appropriate, if carried out during the stage,
i) a description of the use of the genetically modified organism or product during the stage, including extraordinary events and accidents,
j) results obtained during the stage and evaluation thereof.

(9) For the time period laid down in § 3 par. 7 letter b) of the Act, the following shall also be kept:

a) records of training of employees, the instructions thereof and acquaintance with the code of practice of the workplace pursuant to § 3 par. 7 letter g) of the Act, and
b) records of controls of the occurrence of genetically modified organisms outside of the contained space or property on which use of the genetically modified organisms or products takes or took place.

(10) The keeping of documentation pursuant to this Decree shall not apply on medicinal preparations specified in § 1 par. 2 of the Act.

(11) The special legal regulations[27]) on keeping documentation shall be in no way prejudiced hereby.

§ 7
Legal Force

This Decree shall come into effect on January 1, 2001.

[27]) E.g., Decree No. 230/1999 Coll., laying down proper clinical practice and detailed conditions of clinical evaluation of medicinal substances, Decree No. 74/1998 Coll., laying down proper laboratory practice in the area of medicinal substances, Decree No. 311/1997 Coll., on the breeding and use of experimental animals.

Annex No. 1 to the Decree 374/2000 Coll.

Sample application for entry in the List of Users for contained use of genetically modified organisms

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user

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Date of submission

Summary information for the records

Application for entry in the List of Users for contained use	
User	
Professional consultant	
Workplace	
Genetically modified organism or group of organisms	
Purpose of use	
Period of use	
Risk category	

1. The user
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association
1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant
(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title

2.2 Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. E-mail

3. Purpose and duration of the use of the genetically modified organism

3.1. Purpose of the use of the genetically modified organism
3.2. Expected result
3.3. Individual stages in the use and the duration thereof
3.4. Overall time of use

4. Result of risk assessment - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

5. Workplace at which the use will take place

(+) The code of practice of the workplace supplemented pursuant to § 3 par. 7 letter f) and Annex No. 2 to the Act
(+) The emergency response plan pursuant to § 5 of the Act
(+) Document of granting of certification pursuant to § 15 par. 2 of Act No. 246/1992 Coll., on protection of animals against cruelty, and the experiment plan § 23 par. 1 letter a) of Act No. 246/1992 Coll. for facilities for animals

5.1. Address
5.2 Character of the workplace
microbiological laboratory
microbiological activity[1]
pilot plant
production unit
glasshouse / growing-room
facility for animals
other (specify)
5.3. Description of location of the space for contained use and technical description of the facilities thereof
(+) plans of the space and the location of the most important facilities
5.4. Assessment of the space and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures as laid down for the individual risk categories by Decree No. 373/2000 Coll.
(+) Comparison table of requirements for the given category as laid down by the Decree and the actual equipping of the workplace
5.5 The contact person for the given workplace
5.5.1. Name, surname, title
5.5.2. Contact

6. The organism or group of organisms, as appropriate, pursuant to § 7 par. 3 of the Act

6.1. Information on the donor organism, including its origin
6.2. Information on the recipient or parental organism, including the origin thereof
6.3. Information on the vector, including the origin thereof
6.4. Information on the insert
6.5. Method of incorporating the insert
6.6. Information on the genetically modified organism
6.6.1. Function of the inserted or deleted genes, as appropriate
6.6.2. Information permitting unambiguous identification of the altered heritable material
6.6.3. The procedure of detection of the presence of the genetic modification, including the technique of molecular biology
6.7. The approximate amount of genetically modified organisms to be used (volume of the culture, number of plants or animals)
6.8. Information on whether the genetically modified organism involved has already been registered/approved in some other country and for what purpose.

(Not all the information required in Part 6 of this Annex need to be known for cases subject to § 7 par. 3 of the Act).

7. Description of the use of the genetically modified organism

7.1. In case of import or export of the genetically modified organism
7.1.1. The country of origin or destination, as appropriate
7.1.2. Importer or exporter, as appropriate
7.1.3. Maximum imported or exported volume
7.1.4 Means of transportation
7.2. Description of the use of the genetically modified organism in accord with the risk assessment
7.3. Measures to protect the health of humans and animals, the environment and biological diversity
7.4. Information on the system of carrying out control of the occurrence of genetically modified organisms
7.4.1. inside the contained space
7.4.2. outside the contained space
7.5. The manner of inactivation of the genetically modified organism and control of the effectiveness of inactivation thereof
7.6. Description of management of wastes, including hazardous wastes, waste waters and waste gaseous products.

8. Supplementary information

8.1. Manner of keeping documentation on the use of the genetically modified organism and product and the site of depositing thereof
8.2. Plan of training of employees prior to commencing the use of the genetically modified organism or product and the subsequent instruction thereof.

Footnote:

[1] All workplaces where genetically modified microorganisms are used, without regard to the final modified organism, are considered to constitute microbiological activities. Microbiological activities may consist of a laboratory, greenhouse or breeding facility where work is carried out with genetically modified microorganisms.

Annex No. 2 to the Decree 374/2000 Coll.

Sample application for entry in the List of Users for introduction of genetically modified organisms into the environment

(Information denoted (+) must be accompanied by the original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user

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Date of submission

Summary information for the records

Application for entry in the List of Users for introduction into the environment	
User	
Professional consultant	
Workplace or properties	
Genetically modified organism	
Purpose of use	
Period of use	

1. The user
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association
1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant
(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2 Profession, and employer and position, as appropriate

2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. E-mail

3. Purpose and duration of the use of the genetically modified organism
3.1. Purpose of the use of the genetically modified organism
3.2. Expected result
3.3. Individual stages in the use and the duration thereof
3.4. Overall time of use

4. Result of risk assessment - classification in a risk category
(+) Risk assessment pursuant to § 4 of the Act

5. Workplace or properties at which the use will occur
(+) The code of practice of the workplace supplemented pursuant to § 3 par. 7 letter f) and Annex No. 2 to the Act
(+) The emergency response plan pursuant to § 5 of the Act
5.1. The address of the workplace or the position of the properties, as appropriate
(+) copy of the map with designation of the property
5.2 Description of the properties on which the GMOs will be introduced into the environment
5.3. Size of the area on which the GMOs will be introduced into the environment
5.4. Character of the locality (use of surrounding properties, flora, fauna, distance from water courses, protected territories, etc.)
5.5. Measures for the protection of the health of humans and animals, the environment and biological diversity (e.g. safeguarding of properties against trespassing by unauthorized persons, animals, measures preventing the spread of the genetically modified organisms outside of the property)
5.6. The contact person for the given workplace
5.5.1. Name, surname, title
5.5.2. Contact information

6. The organism
6.1. Information on the donor organism, including the origin thereof
6.2. Information on the recipient or parental organism, as appropriate, including the origin thereof
6.3. Information on the vector, including its origin
6.4. Information on the insert
6.5. Method of incorporating the insert
6.6. Information on the genetically modified organism
6.6.1. Function of the inserted or deleted genes
6.6.2. Information permitting unambiguous identification of the altered genetic material
6.6.3. The manner of detection of the presence of the genetic modification

6.7. The approximate amount of genetically modified organisms to be used
6.8. Information on whether the genetically modified organism involved has already been registered/approved in some other country and for what purpose.

7. Description of the use of the genetically modified organism

7.1. In case of import or export of the genetically modified organism
7.1.1. The country of origin or destination, as appropriate
7.1.2. The importer or exporter, as appropriate
7.1.3. The maximum imported or exported volume
7.1.4. The means of transportation
7.2. Description of the use of the genetically modified organism during its introduction into the environment and after completion thereof in accord with the risk assessment
7.3. Information on the system of carrying out control of the occurrence of genetically modified organisms on the property and in its vicinity
7.4.1. during the introduction into the environment
7.4.2. after terminating of the introduction into the environment
7.4. The manner of inactivation of the genetically modified organism and control of the effectiveness of inactivation
7.5. Description of management of wastes

8. Supplementary information

8.1. Means of keeping documentation on the use of the genetically modified organism and product and the site of deposition thereof
8.2. Plan of training of employees prior to commencing the use of the genetically modified organism or product and the subsequent instruction thereof.

Annex No. 3 to the Decree 374/2000 Coll.

Sample application for entry in the List of Users for placing of genetically modified organisms and products on the market

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user

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Date of submission

Summary information for the records

Application for entry in the List of Users for placing on the market	
User	
Professional consultant	
Genetically modified organism	
Product	
Duration of placing on the market	

1. The user
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment of association
1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant
(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2. Profession, and employer and position, as appropriate
2.3. Education

2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. E-mail

3. Purpose and duration of the use of the genetically modified organism or product
3.1. Purpose of placing the genetically modified organism or product on the market
3.2. Individual stages in the use and the duration thereof
3.3. Overall time of placing on the market

4. Result of risk assessment - classification in a risk category
(+) Risk assessment pursuant to § 4 of the Act

5. The organism
5.1. Information on the donor organism, including the origin thereof
5.2. Information on the recipient or parental organism, including the origin thereof
5.3. Information on the vector, including its origin
5.4. Information on the insert
5.5. Method of incorporating the insert
5.6. Information on the genetically modified organism
5.6.1. Function of the inserted or deleted genes, as appropriate
5.6.2. Information permitting unambiguous identification of the altered heritable material
5.6.3. The manner of control of the presence of the genetic modification, including techniques of molecular biology
5.7. The approximate amount of genetically modified organisms to be used
5.8. Information on whether the genetically modified organism or product involved has already been registered/approved in some other country and for what purpose
5.9. If the genetically modified organism of interest has been entered in the List of genetically modified organisms registered for introduction into the environment, the date and number of the decision on entry

6. The product
6.1. Specification of the product
6.2. The manner of use
6.3. Information permitting unambiguous identification of the altered genetic material
6.4. The manner of control of the presence of the genetic modification, including techniques of molecular biology
6.5. Approval of the product in another country and for what purposes
6.6. Packaging
6.7. Labelling
6.8. Information for the consumer
6.9. Further information pursuant to the special regulations (e.g. Act No. 110/1997 Coll., on food and tobacco products, Act No. 91/1996 Coll., on feeds, Act No. 92/1996 Coll., on varieties,

seeds and seedlings of cultivated plants, Act No. 79/1997 Coll., on medicinal substances and supplementing some related Acts)

7. The use of the genetically modified organism or product

7.1. In case of import or export of the genetically modified organism
- 7.1.1. The country of origin or destination, as appropriate
- 7.1.2. The importer or exporter, as appropriate
- 7.1.3. The estimated imported or exported amount
- 7.1.4. The means of transportation

7.2. Measures for protection of the health of humans and animals, the environment and biological diversity (including measures to prevent dissemination of the genetically modified organism and the means of eliminating the genetically modified organism in case of dissemination thereof in the environment)

7.3. The manner of inactivation of the genetically modified organism or product

7.4. Description of management of wastes

7.5. Information on potential interactions of the genetically modified organism or product with the environment

8. Supplementary information

8.1. The means of keeping documentation on the use of the genetically modified organism and product and the site of deposition thereof

8.2. The manner and frequency of taking and analyzing samples after placing on the market

8.3. Monitoring of the effects of the genetically modified organism or product after placing on the market, on the health of humans and animals, the environment and biological diversity (monitoring), if this will be carried out

8.4. The means and frequency of informing the Ministry thereof.

Annex No. 4 to the Decree 374/2000 Coll.

Sample application for entry in the List of genetically modified organisms registered for contained use

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

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Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for contained use	
Genetically modified organism	
Genetic modification	
Risk category	
User	
Purpose of use	
Period of use	

1. The user
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association
1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant
(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience

2.1. Name, surname, title
2.2 Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. E-mail

3. Purpose of the use of the genetically modified organism or product

3.1. Purpose of the contained use of the genetically modified organism
3.2. Expected result

4. Duration of the contained use of the GMO

Binding schedule (description of the individual stages and the duration thereof)

5. Information on (A) the donor organism, (B) the recipient and (where appropriate) (C) the parental organism

(state separately for A, B and C, as appropriate)

5.1. The organism is a
viroid
RNA virus
DNA virus
bacteria
fungus (mould, yeast)
higher plant
animal
other (specify)

5.2. Name (unless a higher plant is involved /Gymnospermae and Angiospermae/)
5.2.1. The order or higher taxon
5.2.2. The genus
5.2.3. The species
5.2.4. The subspecies
5.2.5. The strain (for microorganisms)
5.2.6. The common name (Czech, Latin)

5.3. Name (where a higher plant is involved /Gymnospermae and Angiospermae/)
5.3.1. The family name
5.3.2. The genus
5.3.3 The species
5.3.4. The subspecies
5.3.5. The variety / breeding line
5.3.6. The common name (Czech, Latin)

5.4. The origin (collection, collection number, supplier)

5.5. The geographic distribution of the organism
5.5.1. Natural occurrence in CR
5.5.2. Natural occurrence in Europe including the ecological system
(arctic, Atlantic, Mediterranean, continental)
5.5.3 Natural habitat of the organism
Microorganisms
aquatic environment
soil,
soil in connection with the root system of plants
in connection with the parts of plants above the soil
in connection with animals
other
Plants
natural habitat
agro-ecosystem
Animals
natural habitat
agro-ecosystem
5.5.4. Used or cultivated in CR
5.5.5. Used or cultivated in Europe
5.6. If the organism is pathogenic or otherwise harmful (living or nonliving, including extracellular products), state whether in relation to
humans
animals
plants
5.7. Information on whether there is natural exchange of heritable material between the donor organism and the recipient

6. Information on the genetic modification
6.1. The type of genetic modification
incorporation of foreign heritable material
deletion of part of the heritable material
combination of deletion and incorporation of heritable material
cell fusion
other (specify)
6.2. Intended result of the genetic modification
6.3. Information on the vector used, if used in the genetic modification
(+ genetic map of the vector)
6.3.1. Information on whether the vector is fully or partly present in the final GMO
6.3.2. Type of vector
plasmid
bacteriophage
virus
cosmid
phasmid
transposon

other object (specify)

6.3.3. Identity of the vector

6.3.4. Spectrum of the vector hosts

6.3.5. Presence of the sequence in the affected vector, which transfers the selectable or identifiable phenotype

resistance to antibiotics
resistance to heavy metals
resistance to pesticides (specify)
other resistance (specify)

6.3.6. Methods of incorporation of the vector into the recipient organism

transformation
electroporation[1]
macro-injection
micro-injection
infection
other (specify)

6.3.7. Fragments of the vector and their presence in the final GMO

6.4. If a vector was not used in the genetic modification, the method of incorporating the insert into the recipient organism

transformation
micro-injection
micro-encapsulation
macro-injection
other (specify)

7. Information on the insert

(Summarize information ad 7.1 to 7.3 in a table, + genetic map of the insert)

7.1. Composition of the insert

7.2. Source of each part of the insert

7.3. Intended function of each individual part of the insert in the final GMO

7.4. Location of the insert in the final GMO

on the free plasmid
integrated into the chromosome
other (specify)

7.5. Information on whether the insert contains any part whose products or functions are not known

7.6. Information on whether the sequences contained in the insert participate in any way in pathogenic or harmful properties of the donor organism or vector

8. Information on the resultant genetically modified organism

8.1. Genetic properties and phenotypic characteristics of the recipient or parental organism, that were altered as a result of the genetic modification

8.1.1. Information on whether the genetically modified organism differs from the recipient or parental organism in its survivability

8.1.2. Information on whether the genetically modified organism differs from the recipient

or parental organism in the manner or rate of reproduction
8.1.3. Information on whether the genetically modified organism differs from the recipient or parental organism in its ability to disseminate in the environment
8.2. The genetic stability of the genetically modified organism
8.3. Information on whether the genetically modified organism (living or nonliving, including its extracellular products) is pathogenic or otherwise harmful
if so, in relation to
humans
animals
plants
8.4. Description of methods for identification and detection of the GMO
8.4.1. Methods used to detect the GMO
8.4.2. Methods used to detect the GMO in the environment
8.4.3. Methods permitting unambiguous identification of the altered section of the heritable material.

9. The results of risk assessment of contained use of the GMO - classification in a risk category
(+) Risk assessment pursuant to § 4 of the Act

10. Workplace at which the contained use will occur
(+) The emergency response plan pursuant to § 5 of the Act
(+) The code of practice of the installation pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act
10.1. The address
10.2. The character of the workplace
microbiological workplace
microbiological activities[2]
pilot plant
production unit
glasshouse / growth room
experimental facility for animals (information on granting of certification and the plan of experiments pursuant to Act No. 246/1992 Coll., on protection of animals against cruelty)
other (specify)
10.3. Description of location of the premises for contained use and a technical description of the facilities thereof
(+) plans of the location of the space and the location of selected facilities
10.4. Assessment of the space and the facilities of the workplace and its location pursuant to the requirements on a contained space and protective measures as laid down for the individual risk categories by Decree No. 373/2000 Coll.
(+) Comparison table of requirements for the given category as laid down by the Decree and the actual equipping of the workplace

11. Description of the use of the genetically modified organism in accord with the risk assessment

12. Measures for the protection of the health of humans and animals, the environment and

biological diversity, including the manner of inactivation of the genetically modified organism and control of the effectiveness of the inactivation

13. System of carrying out control of the occurrence of genetically modified organisms during the use of the GMOs and after completion thereof

13.1. The manner and frequency of carrying out controls inside the contained space

13.2. The manner and frequency of carrying out controls outside the contained space

14. Description of waste management

14.1. Solid wastes

14.2. Liquid wastes

14.3. Gaseous wastes

Footnote:

[1] Electroporation means the method of incorporating foreign DNA or chromosomes into cells through the effect of a short voltage pulse, which temporarily increases the permeability of the membrane and thus allows the cells to absorb DNA or chromosomes from the surrounding solution.

[2] All workplaces where genetically modified microorganisms are used, without regard to the final modified organism, are considered to constitute microbiological activities. Microbiological activities may consist in a laboratory, glasshouse or animal facility where work is carried out on genetically modified microorganisms.

Annex No. 5 to the Decree 374/2000 Coll.

Sample application for entry in the List of genetically modified organisms registered for introduction into the environment
for genetically modified microorganisms (GMM)

(Information denoted (+)must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

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Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for introduction into the environment	
Genetically modified organism	
Genetic modification	
Result of risk assessment	
User	
Purpose of introduction into the environment	
Place of introduction into the environment	
Duration of use	

1. The user submitting the application
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association
1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2. Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. E-mail

3. Purpose of the use of the genetically modified organism or product
3.1. Purpose of releasing the GMM into the environment
3.2. Expected result of releasing the GMM into the environment

4. Duration of the release of the GMM into the environment
Binding schedule (description of the individual stages and the duration thereof)

5. Identification information on other users who will carry out release of the GMM into the environment or will participate therein
(+)Officially authenticated copies of the decision on entry of these persons into the List of Users or applications of these persons for entry into the List of Users
5.1. The user
5.2. The work that (s)he will carry out

6. Information on (A) the donor organism, (B) the recipient and (where appropriate) (C) the parental organism
(state separately for A, B and C, as appropriate)
6.1. Name
6.1.1. The order
6.1.2. The genus
6.1.3. The species
6.1.4. The subspecies
6.1.5. The strain
6.1.6. The common name (Czech, Latin)
6.2. The origin (collection, collection number, supplier)
6.3. Plasmids
6.4. Bacteriophages
6.5. Phenotypic and genetic signal markers
6.6. Degree of relatedness between the donor organism and the recipient
6.7. Methods of identification and detection
6.7.1. Description of the methods
6.7.2. Sensitivity, reliability (in quantitative terms) and specificity of identification and detection methods

6.8. Occurrence and living conditions
6.8.1. Geographic distribution
6.8.2. The natural habitat of the organism
aquatic environment
soil,
soil in connection with the root system of plants
in connection with the parts of plants above the soil
in connection with animals
other
6.8.3. Natural predators, preys, parasites and competitors, symbionts and hosts
6.8.4. Other potential interactions with other organisms
6.9. Potential intercellular transfer of genetic material
6.9.1. Means of transfer (plasmid, bacteriophage, other)
6.9.2. Organisms with which natural exchange of genetic material occurs
6.10. Verification of the genetic stability of the organism and the factors that affect this stability
6.11. Reproduction
6.11.1. Means of reproduction
6.11.2. Specific factors affecting reproduction (if any)
6.11.3. Generation time in the natural environment
6.12. Survivability
6.12.1. Survivability in the individual seasons
6.12.2. Ability to form survival structures, such as seeds, spores, sclerotia
6.12.3. Other specific factors enabling survival
6.13. Dissemination in the environment
6.13.1. Means and extent of dissemination
6.13.2. Specific factors affecting dissemination
6.14. Effects of a living or nonliving organism (including extracellular products) on the health of humans, animals and other organisms
pathogenicity: contagiousness, infectivity, virulence
allergic effects
toxic effects
carrier of pathogen
possible activation of latent viruses (proviruses)
ability to penetrate into other organisms or colonize other organisms
antibiotic resistance and potential use of these antibiotics for prophylaxis and treatment of diseases of humans and animals
other (specify)
6.15. Involvement in environmental processes
primary production
nutrient turnover
decomposition of organic matter
other (specify)
6.16. Indigenous vectors of the organism
6.16.1. sequence
6.16.2. frequency of mobilization
6.16.3. specificity

6.16.4. presence of genes conferring resistance
6.17. Previous genetic modifications

7. Information on the genetic modification

7.1. The type of genetic modification
- insertion of foreign heritable material
- deletion of part of the heritable material
- combination of deletion and incorporation of heritable material
- cell fusion
- other (specify)

7.2. Intended result of the genetic modification
7.3. Information on the vector used, if used in the genetic modification
(+ genetic map of the vector)
7.3.1. Information on whether the vector is fully or partly present in the final GMM
7.3.2. Type of vector
- plasmid
- bacteriophage
- virus
- cosmid
- phasmid
- transposon
- other object (specify)

7.3.3. Identity of the vector (origin)
7.3.4. Spectrum of the vector hosts
7.3.5. Presence of the sequence in the vector in question, which transfers the selectable or identifiable phenotype
- resistance to antibiotics
- resistance to heavy metals
- resistance to pesticides (specify)
- other resistance (specify)

7.3.6. Methods of incorporation of the vector into the recipient organism
- transformation
- electroporation[1]
- macro-injection
- micro-injection
- infection
- other (specify)

7.3.7. Information on the degree to which the vector is limited to the sequence of the nucleic acid required to perform the intended function.
7.3.8. Fragments of the vector and their presence in the final GMM
7.4. If a vector was not used in the genetic modification, the method of incorporating the insert into the recipient organism
- transformation
- micro-injection
- micro-encapsulation
- macro-injection

other (specify)

7.5. Methods and criteria used for selection

8. Information on the insert

8.1. Information on each part of the insert or each eliminated part of the heritable material with special emphasis on any known harmful sequences
- 8.1.1. size
- 8.1.2. position
- 8.1.3. sequence
- 8.1.4. origin
- 8.1.5. functional characteristics

8.2. Purity of the insert
- 8.2.1. Information on whether the insert contains a part whose products or functions are not known
- 8.2.2. Information on the degree to which the insert is limited to the sequence of the nucleic acid required to perform the intended function

8.3. Information on whether the sequences contained in the insert participate in any way in pathogenic or harmful properties of the donor organism or vector.

9. Information on the resultant genetically modified organism

9.1. Description of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification

9.2. Information on the altered section of the nucleic acid
- 9.2.1. Structure and size of each section of the nucleic acid derived from the vector and/or donor organism remaining in the final GMM, including methods and information required for identification and detection of the inserted sequence
- 9.2.2. In case of deletion of part of the heritable material, the size and function of the deleted nucleic acid segment
- 9.2.3. The location of the inserted genetic material in the cell
- 9.2.4. The number of copies of the inserted genetic material
- 9.2.5. The stability of the location thereof

9.3. The genetic stability of the GMM according to the heritable properties

9.4. Expression of the inserted heritable material
- 9.4.1. Rate and degree of expression of the new heritable material
- 9.4.2. Description of the methods of measurement, giving its sensitivity
- 9.4.3. The stability of the expression

9.5. Expressed proteins
- 9.5.1. Activity of the expressed proteins
- 9.5.2. Description of identification and detection methods, giving their sensitivity, reliability and specificity

9.6. Health factors
- 9.6.1. Toxic or allergic effects of the genetically modified organism or its metabolic products
- 9.6.2. Comparison of the modified organism with the donor organism, recipient or (where appropriate) parental organism, regarding pathogenicity
- 9.6.3. Ability to colonize / penetrate into other organisms
- 9.6.4. If the organism is pathogenic to human individuals who are immunocompetent:

9.6.4.1. diseases caused and mechanism of pathogenicity including invasiveness and virulence
9.6.4.2. communicability / infectiousness
9.6.4.3. infective dose
9.6.4.4. host range, possibility of alteration
9.6.4.5. possibility of survival outside the human host
9.6.4.6. presence of vectors or means of dissemination
9.6.4.7. biological stability
9.6.4.8. antibiotic-resistance patterns
9.6.4.9. allergic effects
9.6.4.10. availability of appropriate therapy
9.6.4.11. other risks

9.7. Information on the way in which the GMM differs from the parental microorganism
means and rate of multiplication
dissemination in the environment
survivability
effects on the health of humans, animals and other organisms
other (specify)

9.8. Previous use of the GMM

9.9. Description of methods of identification and detection of the GMM
9.9.1. Methods used to detect the GMM
9.9.2. Methods used to identify the GMM in the environment
9.9.3. Information permitting unambiguous identification of the altered section of the heritable material

10. Result of risk assessment of contained use of the GMM - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

11. Information on release of the GMM into the environment in other countries

11.1. Information on whether the GMM has already been registered/approved for introduction into the environment (where possible, state the number or designation of the registration)
11.1.1. Country
11.1.2. User / applicant / notifier (pursuant to the EC Directive)
11.1.3. Purpose of introduction into the environment
11.1.4. Period in time

11.2. Information on whether release of the GMM into the environment is planned in another country
11.2.1. Country
11.2.2 User / applicant / notifier (pursuant to the EC Directive)
11.2.3. Purpose
11.2.4. Date

12. Information on the amount of GMM to be used and on the total area of the properties

12.1. Approximate amount of GMM to be used

12.2. Total extent of the area over which the release of the GMM into the environment is to occur

13. Workplace and properties at which the introduction into the environment will occur

(+) The emergency response plan pursuant to § 5 of the Act

(+) The code of practice of the workplace pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act

(+) Copies of the maps

13.1. The user who will carry out release of the GMM on the given property, and the owner of the property

13.2. Address (location)

13.3. Contact person for the given property

13.3.1. Name, surname, title

13.3.2. Contact

13.4. Specification of the property

13.4.1 Municipality

13.4.2. District

13.4.3. Position of the area for cultivation of the GMM on the property and the size thereof (+ plan on a suitable scale)

13.4.4. Size and use of the isolation zone around the area for cultivation of the GMM (+ denote on the plan)

13.4.5. Use of the surrounding properties

13.5. Distance from specific territories

13.5.1. Specially protected territories (Act No. 114/1992 Coll., on protection of nature and the landscape, as amended)

13.5.2. Protective zones of water sources

13.5.3. Water courses, water reservoirs

13.5.4. Other

13.6. Safeguarding the property

13.6.1. Safeguarding against unauthorized persons

13.6.2. Safeguarding against animals

13.6.3. Safeguarding against water runoff

13.7. Description of the ecosystem at the site of the property

13.7.1. Type of soil

13.7.2. Water regime including irrigation

13.7.3. Climatic conditions

13.7.4. Flora including agricultural crops

13.7.5. Fauna including domestic and migrating animals

13.8. Description of target and nontarget ecological systems likely to be affected

13.9. Comparison of the natural habitat of the recipient or parental organism, as appropriate, with the proposed site of release of the GMM into the environment

13.10. Any known planned changes in the use of the properties in the vicinity of the site of release of the GMM into the environment that are likely to affect the environmental impact of the GMM

14. Description of the use of the GMM

14.1. Use of the GMM prior to its introduction into the environment (contained use, transportation)

14.2. Procedure through which the GMM will be released into the environment

14.3. Approximate number of GMM (per m^2 or m^3)

14.4. Preparation and treatment of the property prior to application of the GMM
14.5. Cultivation of the GMM on the property
14.6. Elimination of the GMM from the environment
14.7. Further use of the GMM including inactivation thereof
14.8. Date and manner of evaluation of the release of the GMM into the environment

15. Measures to protect the health of humans and animals, the environment and biological diversity, including the manner of disposal of the genetically modified organism and control of the effectiveness of the disposal and waste management

15.1. Monitoring of the occurrence and effects of the GMM
15.1.1. Methods of determining the presence of GMM and monitoring of their effects
15.1.2. Specificity of methods of identification of GMM and differentiation of GMM from the donor organisms, recipients, or parental organisms, as appropriate, sensitivity and reliability of these methods
15.1.3. Techniques (methods) of detection of transfer of the inserted heritable material to other organisms
15.2. Measures adopted to prevent spread of the GMM to the environment during introduction into the environment
15.2.1. Technical measures
15.2.2. Plan of controls and supervision
15.3. Measures adopted to minimize the occurrence of the GMM on the property and in its vicinity after termination of the release of the GMM into the environment
15.3.1. Description of methods for treating the property after terminating the experiment
15.3.2. Plan of controls and supervision
15.3.3. Means of inactivation of the GMM and control of the efficiency thereof
15.4. Manner of transport of the GMM
15.5. Protection of the health of employees during use of the GMM
15.6. Waste management
15.6.1. Kinds of wastes formed and the expected amounts thereof
15.6.2. Potential risks from waste management
15.6.3. Description of waste disposal and methods of controlling the effectiveness of the disposal thereof

16. Information on interactions between the GMM and the environment

16.1. Survival, multiplication and dispersal
16.1.1. Properties of the GMM that affect survival, multiplication and dispersal of the GMM in the environment
16.1.2. Known or predicted environmental conditions that could affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.)
16.1.3. Sensitivity to specific substances (agents)
16.2. Predicted habitat of the GMM
16.3. Results of studies of the behaviour and properties of the GMM and their environmental impacts carried out in a simulated natural environment
16.4. Genetic transfer capability
16.4.1. Possibility of post-release transfer of heritable materials from GMMs into other organisms

16.4.2. Possibility of post-release transfer of heritable material from indigenous organisms to the GMM
16.5. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMM
16.6. Genetic stability of GMM in the environment
16.6.1. Measures to ensure genetic stability
16.6.2. Description of genetic traits which are supposed to prevent or limit dispersal of the genetic material
16.6.3. Methods of verifying the genetic stability
16.7. Routes of biological dispersal of the GMM, known or potential modes of interaction with the disseminating agents (inhalation, ingestion, surface contact, etc.)
16.8. Ecosystems into which the GMMs could be disseminated
16.9. Potential for excessive increase in the population of GMM in the environment
16.10. Competitive advantage of the GMMs in relation to the recipient or parental organism, as appropriate
16.11. Identification and description of the target organisms, if any
16.12. Anticipated mechanism and result of interaction between the GMMs and the target organism, if a target organism exists
16.13. Identification and description of nontarget organisms which could be detrimentally affected by release of the GMM into the environment and the expected mechanism of determined undesirable impacts
16.14. Likelihood of post-release shifts in biological interactions or in the host range
16.15. Known of predicted interactions with nontarget organisms in the environment, including competitors, preys, hosts, symbionts, predators, parasites and pathogens
16.16. Known or predicted involvement in biogeochemical processes
16.17. Likelihood that the GMMs will become more resistant or more invasive than the recipient in the environment
16.18. Other potential impacts on the environment and biological diversity.

17. Provision of samples and necessary information for detection of the altered heritable material

(Specification of the samples provided to the workplace carrying out the detection, the amount, frequency and means of supply thereof)

17.1. Prior to commencement of the use
17.2. During the use

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[1] Electroporation means the method of incorporating foreign DNA or chromosomes into cells through the effect of a short voltage pulse, which temporarily increases the permeability of the membrane and thus allows the cells to absorb DNA or chromosomes from the surrounding solution.

Annex No. 6 to the Decree 374/2000 Coll.

Sample application for entry in the List of genetically modified organisms registered for introduction into the environment for genetically modified higher plants (GMHP)

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

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Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for introduction into the environment	
Genetically modified organism	
Genetic modification	
Result of risk assessment	
User	
Purpose of introduction into the environment	
Place of introduction into the environment	
Duration of use	

1. The User submitting the application
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2. Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. e-mail

3. Purpose of the use of the genetically modified organism or product
3.1. Purpose of releasing the GMHP into the environment
3.2. Expected result of releasing the GMHP into the environment

4. Duration of the release of the GMHP into the environment
Binding schedule (description of the individual stages and the duration thereof)

5. Identification information on other users who will carry out release of the GMHP into the environment or will participate therein
(+)Officially authenticated copies of the decisions on entry of these persons into the List of Users or of applications of these persons for entry into the List of Users
5.1. The user
5.2. The work that (s)he will carry out

6. Information on (A) the recipient and (where appropriate) (B) the parental plant
(state separately for A and B, as appropriate)
6.1. Name
6.1.1. The order
6.1.2. The genus
6.1.3. The species
6.1.4. The subspecies
6.1.5. The variety, breeding line
6.1.6. The Czech name, Latin name
6.2. The origin (collection, collection number, supplier)
6.3. Reproduction
6.3.1. Modes of reproduction
6.3.2. Specific factors affecting reproduction (if any)
6.3.3. Generation time
6.3.4. Sexual compatibility with other cultivated or wild species and distribution of these compatible species in CR
6.4. Survivability
6.4.1. Ability to form structures enabling survival or dormancy and the length of potential survival or dormancy

6.4.2. Further specific factors enabling survivability, if any
6.5. Dissemination of the plant in the environment
6.5.1. Ways and extent of spreading (decrease in the amount of pollen and seeds in dependence on distance from the source)
6.5.2. Specific factors affecting spreading (if any)
6.6. Geographical distribution of the plant
6.7. If the plant is not cultivated in CR, a description of the natural habitat, including information on natural enemies (predators), parasites, competitors and symbionts
6.8. Other potentially significant interactions of the plant with other organisms in the ecosystem where it is usually cultivated, and elsewhere
6.9. Effects on the health of humans, animals and other organisms
toxicity
allergenicity
other (specify)

7. Information on the genetic modification
7.1. The type of genetic modification
incorporation of foreign heritable material
deletion of part of the heritable material
combination of deletion and incorporation of heritable material
other (specify)
7.2. Description of the methods used in the genetic modification
7.3. Properties and origin of the vector used (if a vector was used in the genetic modification) (+ map of the vector)
7.4. Information on each part of the section of the DNA that was inserted into the organism of the recipient (if the genetic modification includes insertion of heritable material)
7.4.1. Size
7.4.2. Position - if integrated
7.4.3. Sequence
7.4.4. Origin (name of the donor organism)
7.4.5. Functional characteristics

8. Information on the genetically modified higher plant
8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification
8.2. Information on the DNA section that was inserted or deleted
8.2.1. Structure and size of the DNA insert, including information on each vector section inserted into the GMHP, or on any carrier or foreign DNA remaining in the GMHP,
8.2.2. In case of deletion of part of the heritable material, the size and function of the part of the deleted nucleic acid segment
8.2.3. The location of the inserted heritable material in the plant cell (integrated in the chromosome, chloroplast, mitochondria or in a non-integrated form)
8.2.4. The number of copies of the inserted heritable material
8.2.5. The stability of the inserted heritable material and the stability of its location
8.2.6. Methods of determining the data set forth in points 8.2.1 to 8.2.5.
8.3. Information on expression of the inserted heritable material

8.3.1. Methods used for characterization of the expression
8.3.2. Parts of the plant where the insert is expressed (e.g., roots, stem, leaves, pollen, etc.)
8.3.3. Changes in expression in dependence on the life cycle of the plant
8.3.4. Stability of the expression
8.4. Information permitting unambiguous identification of the GMHP
8.4.l. Description of the altered part of the DNA
8.4.2. Methods of detection and identification of the GMHP, including methods of molecular biology
8.5. Behaviour of the inserted genes
8.5.1. during hybridization with the same species
8.5.2. during hybridization with distant species
8.6. Information on how the GMHP differs from the recipient or parental organism
mode and rate of reproduction
spreading in the environment
survivability
effects on the health of humans, animals and other organisms
other (specify)
8.7. Phenotypical stability of the GMHP
8.8. Ability of the GMHP to transfer genetic material to other organisms
8.9. Information on any potential harmful effects of the GMHP on human health arising from the genetic modification
8.10. Information on the safety of the GMHP for animal health, particularly in relation to any harmful effects arising from the genetic modification, if the GMHP is to be used as feedingstuff
8.11. Mechanism of interaction between the genetically modified plant and the target organism, if a target organism exists
8.12. Potential changes in the interactions of the GMHP with nontarget organisms arising from the genetic modification
8.13. Potential interaction with nonliving components of the environment.
8.14. Results of previous releases of the GMHP into the environment

9. Result of risk assessment of release of the GMHP into the environment - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on release of the GMHP into the environment in other countries

10.1. Information on whether the GMHP has already been registered/approved for introduction into the environment (where possible, state the number or designation of the registration)
10.1.1. Country
10.1.2. User / applicant / notifier (pursuant to the EC Directive)
10.1.3. Purpose of introduction into the environment
10.1.4. Period in time
10.2. Information on whether release of the GMHP into the environment is planned in another country
10.2.1. Country
10.2.2 User / applicant / notifier (pursuant to the EC Directive)

10.2.3. Purpose
10.2.4. Date

11. Information on the amount of GMHP to be used and on the total area of the properties

11.1. Approximate amount of GMHP to be released into the environment
11.2. Total extent of the area over which the release of the GMHP into the environment is to occur

12. Workplace and properties at which the introduction into the environment will occur

(+) The emergency response plan pursuant to § 5 of the Act
(+) The code of practice of the workplace pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act
(+) Copies of the maps
If all the information required in point 12 cannot be stated in the application for the entire period of release of the GMHP into the environment, the absent information must always be submitted to the Ministry at the latest 30 days before commencement of release of the GMHP into the environment

12.1. The user who will carry out release of the GMHP on the given property, and the owner of the property
12.2. Address (location)
12.3. Contact person for the given property
12.3.1. Name, surname, title
12.3.2. Contact information (telephone, fax, e-mail)
12.4. Specification of the property
12.4.1 Municipality
12.4.2. District
12.4.3. Name / designation / cadastral number
12.4.4. Position of the cultivation of the GMHP on the property and the size thereof (+ plan on a suitable scale)
12.4.5. Size and use of the isolation zone around the area for cultivation of the GMHP (+ denote on the plan)
12.4.6. Use of the surrounding properties
12.5. Distance from specific territories
12.5.1. Specially protected territories (Act No. 114/1992 Coll., on protection of nature and the landscape, as amended)
12.5.2. Protective zones of water sources
12.5.3. Water courses, water reservoirs
12.5.4. Other
12.6. Safeguarding the property
12.6.1. against unauthorized persons
12.6.2. against animals
12.6.3. against water runoff
12.7. Description of the ecosystem at the site of the property
12.7.1. Type of soil
12.7.2. Water regime including irrigation
12.7.3. Climatic conditions
12.7.4. Flora including agricultural crops
12.7.5. Fauna including domestic and migrating animals

12.8. Presence of wild or cultivated sexually compatible plants on the property and in its vicinity

13. Description of the use of the GMHP

13.1. Use of the GMHP prior to its introduction into the environment (contained use, transportation)
13.2. Procedure through which the GMHP will be released into the environment
13.3. Approximate number of plants per m^2
13.4. Preparation and treatment of the property prior to cultivation of the GMHP
13.5. Cultivation of the GMHP on the property
13.6. Harvesting of the GMHP
13.7. Further use of the GMHP
13.8. Date and manner of evaluation of the release of the GMHP into the environment

14. Measures to protect the health of humans and animals, the environment and biological diversity and waste management

14.1. Distance of the area for cultivation of the GMHP from wild or cultivated sexually compatible species of plants
14.2. Measures to decrease or prevent air-transport of pollen or seeds, if used
14.3. Description of the methods for treatment of the property after the end of the experiment
14.4. Description of the methods for transport and processing of the GMHP
14.5. Description of the plan of control and methods of supervision during release of the GMHP into the environment and after completion thereof
14.6. Waste management including disposal of the GMHP

15. Provision of samples and necessary information for detection of the altered heritable material

(Specification of the samples provided to the workplace carrying out the detection, the amount, frequency and means of supply thereof)

15.1. Prior to commencement of use
15.2. During use

Annex No. 7 to the Decree 374/2000 Coll.

Sample application for entry in the List of genetically modified organisms registered for introduction into the environment
for genetically modified animals (GMA)

(Information denoted (+)must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user and the designation of the genetically modified organism

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Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for introduction into the environment	
Genetically modified organism	
Genetic modification	
Result of risk assessment	
User	
Purpose of introduction into the environment	
Place of introduction into the environment	
Duration of use	

1. The user submitting the application
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant

(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2. Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. E-mail

3. Purpose of the use of the genetically modified organism or product
3.1. Purpose of releasing the GMA into the environment
3.2. Expected result of releasing the GMA into the environment

4. Duration of the release of the GMA into the environment
Binding schedule (description of the individual stages and the duration thereof)

5. Identification information on other users who will carry out release of the GMA into the environment or will participate therein
(+) Officially authenticated copies of the decisions on entry of these persons into the List of Users or of applications of these persons for entry into the List of Users
5.1. The user
5.2. The work that (s)he will carry out

6. Information on (A) the donor organism, (B) the recipient and (where appropriate) (C) the parental organism
(state separately for A, B and C, as appropriate)
6.1. Name
6.1.1. The order
6.1.2. The genus
6.1.3. The species
6.1.4. The subspecies
6.1.5. The variety
6.1.6. The Czech name, Latin name
6.2. The origin (collection, collection number, supplier)
6.3. Phenotypic and genetic markers
6.4. Degree of relatedness between the donor organism and the recipient
6.5. Occurrence and living conditions
6.5.1. Geographical distribution
6.5.2. Habitat (natural occurrence) of the organisms
6.5.3. Natural predators, preys, parasites and competitors, symbionts and hosts
6.5.4. Further potential interactions with other organisms
6.6. Verification of the genetic stability of the organisms and the factors that affect this stability

6.7. Reproduction
6.7.1. Means of reproduction
6.7.2. Specific factors affecting reproduction (if any)
6.7.3. Generation time in the natural environment
6.8. Survivability
6.8.1. Survivability in the individual seasons
6.8.2. Ability to form resistant survival structures
6.8.3. Other specific factors enabling survival, if any
6.9. Dissemination in the environment
6.9.1. Means and extent of spreading
6.9.2. Specific factors affecting spreading (if any)
6.10. Effects of a living or nonliving organism (including metabolic products) on the health of humans, animals and other organisms
pathogenicity/ infectivity
toxic effects
allergic effects
carrier of pathogen
other (specify)
6.11. Spectrum of hosts, including nontarget organisms
6.12. Involvement in environmental processes
primary production
nutrient turnover
decomposition of organic matter
other (specify)
6.13. Description of previous genetic modifications

7. Information on the genetic modification
7.1. The type of genetic modification
insertion of foreign heritable material
deletion of part of the heritable material
combination of deletion and incorporation of heritable material
other (specify)
7.2. Description of the methods used for the genetic modification
7.3. Information on the properties and origin of the vector used (if a vector was used in the genetic modification)
(+ map of the vector)
7.4. Information on each part of the DNA sector inserted into the organism of the recipient (if the genetic modification includes insertion of heritable material)
7.4.1. Size
7.4.2. Position - if integrated
7.4.3. Sequence
7.4.4. Origin (name of the donor organism)
7.4.5. Functional characteristics

8. Information on the genetically modified animal
8.1. Description and characteristics of the heritable properties and phenotypic traits, that were

altered as a result of the genetic modification
8.2. Information on the DNA segment that was inserted or deleted
8.2.1. Structure and size of the inserted DNA, including information on each vector segment that was inserted into the GMA, or on any carrier or foreign DNA remaining in the GMA
8.2.2. In case of deletion of part of the heritable material, the size and function of the each deleted nucleic acid segment
8.2.3. The location of the inserted genetic material in the cell
8.2.4. The number of copies of the inserted genetic material
8.2.5. The stability of the inserted genetic material and the stability of the location thereof
8.2.6. Methods of determining the information specified in points 8.2.1. to 8.2.5.
8.3. Information on expression of the inserted heritable material
8.3.1. Methods used for characterizing the expression
8.3.2. Organs where the inserted genes are expressed
8.3.3. Rate and degree of expression, changes in expression in dependence on the life cycle
8.3.4. The stability of the expression
8.4. Expressed proteins
8.4.1. Activity of the expressed proteins
8.4.2. Description of identification and detection methods, giving their sensitivity, reliability and specificity
8.5. Information enabling unambiguous identification of the GMA
8.5.1. Description of the part of the altered DNA
8.5.2. Methods of detection and identification of the GMA, including methods of molecular biology
8.6. Stability of the GMA according to its heritable properties
8.7. Information on the way in which the GMA differs from the parental microorganism
means and rate of reproduction
dispersal in the environment
survivability
effects on the health of humans, animals and other organisms
other (specify)
8.8. Ability of the GMA to transfer genetic material to other organisms
8.9. Information on every potential harmful effect of the GMA, including its metabolic products, on the health of humans and animals caused by the genetic modification
pathogenicity/ infectivity
toxic or allergic effects
ability to colonize other organisms
other (specify)
8.10. Mechanism of interaction between the GMA and the target organism, if a target organism exists
8.11. Potential changes in the interactions of the GMA with nontarget organisms, following from the genetic modification
8.12. Potential interactions with nonliving components of the environment
8.13. The results of previous use of the GMA

9. Result of risk assessment of contained use of the GMA - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on release of the GMA into the environment in other countries

10.1. Information on whether the GMA has already been registered/approved for introduction into the environment (where possible, state the number of designation of the registration)
- 10.1.1. Country
- 10.1.2. User / applicant / notifier (pursuant to the EC Directive)
- 10.1.3. Purpose of introduction into the environment
- 10.1.4. Period in time

10.2. Information on whether release of the GMA into the environment is planned in another country
- 10.2.1. Country
- 10.2.2 User / applicant / notifier (pursuant to the EC Directive)
- 10.2.3. Purpose
- 10.2.4. Date

11. Information on the amount of GMA to be used and on the total area of the properties

11.1. Approximate amount of GMA to be released into the environment

11.2. Total extent of the area over which the release of the GMA into the environment is to occur

12. Workplace and properties at which the introduction into the environment will occur

(+) The emergency response plan pursuant to § 5 of the Act
(+) The code of practice of the workplace pursuant to § 3 par. 7 letter f) and Annex No. 2 of the Act
(+) Copies of the cadastral maps
If all the information required in point 12 cannot be stated in the application for the entire period of release of the GMA into the environment, the absent information must be submitted to the Ministry at the latest 30 days before commencement of release of the GMA into the environment

12.1. The user who will carry out release of the GMA on the given property, and the owner of the property

12.2. Address (location)

12.3. Contact person for the given property
- 12.3.1. Name, surname, title
- 12.3.2. Contact information (telephone, fax, e-mail)

12.4. Specification of the property
- 12.4.1. Municipality
- 12.4.2. District
- 12.4.3. Name / designation / cadastral number
- 12.4.4. Use of the surrounding properties

12.5. Distance from specific territories
- 12.5.1. Specially protected territories (Act No. 114/1992 Coll., on protection of nature and the landscape, as amended)
- 12.5.2. Protective zones of water sources
- 12.5.3. Water courses, water reservoirs
- 12.5.4. Other

12.6. Safeguarding the property
- 12.6.1. Safeguarding against unauthorized persons

12.6.2. Safeguarding against animals
12.6.3. Safeguarding against runoff
12.7. Description of the ecosystem at the site of the property
12.7.1. Type of soil
12.7.2. Water regime including irrigation
12.7.3. Climatic conditions
12.7.4. Flora including agricultural crops
12.7.5. Fauna including domestic and migrating animals
12.8. Description of target and nontarget ecosystems that could be affected
12.9. Comparison of the natural habitat of the recipient or parental organism, as appropriate, with the proposed site of release of the GMA into the environment
12.10. Any known planned changes in the use of the properties in the vicinity of the site of release of the GMA into the environment that could affect the environmental impact of the GMA

13. Description of the use of the GMA

13.1. Use of the GMA prior to its introduction into the environment (contained use, transportation)
13.2. Procedure through which the GMA will be released into the environment
13.3. Approximate number of GMA per m^2
13.4. Preparation and treatment of the experimental areas prior to use of the GMA
13.5. Use of the GMA on the property
13.6. Elimination of the GMA from the environment
13.7. Further use of the GMA, including its disposal
13.8. Date and manner of evaluation of the release of the GMA into the environment

14. Measures to protect the health of humans and animals, the environment and biological diversity and waste management

14.1. Monitoring of the occurrence and effects of the GMA
14.1.1. Methods of determining the presence of the GMAs and monitoring of their effects
14.1.2. Specificity of the methods of identification of the GMA and differentiating the GMA from the recipient or parental organism, as appropriate, the sensitivity and reliability of these methods
14.1.3. Techniques (methods) of detection of transfer of the inserted heritable material to other organisms
14.2. Measures adopted to decrease the dissemination of the GMA into the environment during the introduction into the environment
14.2.1. Technical measures
14.2.2. Plan of controls and supervision
14.3. Measures adopted to limit the occurrence of the GMA on the property after the end of the introduction into the environment
14.3.1. Description of the method of treatment of the property after the end of the experiment
14.3.2. Plan of controls and supervision
14.3.3. Means of disposal of the GMA and control of the effectiveness of the disposal
14.4. The method for transport of the GMA
14.5. Protection of the health of workers during use of the GMA

14.6. Waste management
14.6.1. Kinds of waste formed and the expected amounts thereof
14.6.2. Potential risks from waste management
14.6.3. Description of waste disposal and methods of controlling the efficiency of this disposal

15. Provision of samples and necessary information for detection of the altered heritable material

(Specification of samples provided to the workplace carrying out the detection, the amount, frequency and means of supply thereof)

15.1. Prior to commencement of use
15.2. During use

Annex No. 8 to the Decree 374/2000 Coll.

Sample application for entry in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic for a genetically modified organism (GMO) other than a higher plant, or for a product containing a GMO other than a higher plant

(Information denoted (+)must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user and the name (designation) of the genetically modified organism

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Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for placing on the market in the Czech Republic	
Genetically modified organism	
Product	
Genetic modification	
Use of the GMO or product	
Conclusions of the risk assessment	
Means of laboratory control of the presence of the genetic modification	
The user who applied for entry of the GMO or product	
Time of use	

1. The user submitting the application
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)
1.9. Statutory body of the user (for legal persons)

1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant
(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2. Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. e-mail

3. Person responsible for supplying control samples after placing the GMO or product on the market - the producer, distributor or importer, as appropriate
3.1. Identification information
3.2. Contact information

4. Commercial name of the GMO or product, any other specifications of the GMO or product, as appropriate

5. Placing the GMO or product on the market
5.1. Use of the GMO or product
5.2. Legal regulations governing the placing of the given GMO or product on the market for the use specified in point 5.1.
5.3. Description of the individual stages in the placing on the market and the duration thereof, including the binding schedule for placing on the market
5.4. Expected amount of GMO or product used in the individual stages, including statement of whether production inside CR or import will be involved.

6. Information on (A) the donor organism, (B) the recipient, and (where appropriate) (C) the parental organism
(state separately for A, B and C, as appropriate)
6.1. Name
6.1.1. The order
6.1.2. The genus
6.1.3. The species
6.1.4. The subspecies
6.1.5. The variety
6.1.6. The Czech name, Latin name
6.2. The origin (collection, collection number, supplier)
6.4. Phenotypic and genetic markers

6.4. For microorganisms, the inherent plasmids, bacteriophages and other
  6.4.1. The sequence
  6.4.2. The frequency of mobilization
  6.4.3. The specificity
  6.4.4. The presence of genes causing resistance
6.5. The degree of relatedness between the donor organism and the recipient
6.6. Methods of identification and detection
  6.6.1. Description of the methods
  6.6.2. Sensitivity, reliability (quantitative) and specificity of the methods
6.7. Occurrence and living conditions
  6.7.1. Geographic distribution
  6.7.2. The habitat (natural area of occurrence) of the organism
  6.7.3. Natural predators, preys, parasites and competitors, symbionts and hosts
  6.7.4. Other potential interactions with other organisms
6.8. Potential intercellular transfer of genetic material
  6.8.1. Means of transfer (plasmid, bacteriophage, other)
  6.8.2. Organisms with which natural exchange of genetic material occurs
6.9. Verification of the genetic stability of the organisms and the factors that affect this stability
6.10. Reproduction
  6.10.1. Means of reproduction
  6.10.2. Specific factors affecting reproduction (if any)
  6.10.3. Generation time in the natural environment
6.11. Survivability
  6.11.1. Survivability in the individual seasons
  6.11.2. Ability to form resistant structures (e.g. seeds, spores, sclerotia)
  6.11.3. Other specific factors enabling survival, if any
6.12. Dissemination in the environment
  6.12.1. Means and extent of spreading
  6.12.2. Specific factors affecting spreading (if any)
6.13. Effects of a living or nonliving organism (including extracellular products) on the health of humans, animals and other organisms
    pathogenicity, infectivity, virulence
    allergic effects
    toxic effects
    carrier of pathogen
    possible activation of latent viruses (proviruses)
    ability to penetrate into other organisms or colonize other organisms
    antibiotic resistance and potential use of these antibiotics in humans and animals for prophylaxis and therapy
    other (specify)
6.14. Spectrum of hosts including nontarget organisms
6.15. Involvement in environmental processes
    primary production
    nutrient turnover
    decomposition of organic matter
    other (specify)

6.16. Description of previous genetic modifications

7. Information on the genetic modification

7.1. The type of genetic modification
- insertion of foreign heritable material
- deletion of part of the heritable material
- combination of deletion and incorporation of heritable material
- other (specify)

7.2. Description of the methods used for the genetic modification

7.3. Information on the vector, if used in the genetic modification (+ genetic map of the vector)
- 7.3.1. Information on whether the vector is fully or partly present in the final GMO
- 7.3.2. Type of vector
- 7.3.3. Identity of the vector (origin)
- 7.3.4. Presence of the sequence in the vector in question, which transfers the selectable or identifiable phenotype
- 7.3.5. Information on the degree to which the given vector is limited to the sequence of the nucleic acid required to perform the intended function.
- 7.3.6. Methods and criteria used for the selection

7.4. Information on each part of the insert or each deleted part of the heritable material with special emphasis on any known harmful sequences
- 7.4.1. Size
- 7.4.2. Position
- 7.4.3. Sequence
- 7.4.4. Origin
- 7.4.5. Functional characteristics

7.5. Purity of the insert
- 7.5.1. Information on whether the insert contains an insert part whose products or functions are not known
- 7.5.2. Information on the degree to which the insert is limited to the sequence of the nucleic acid required to perform the intended function

7.6. Information on whether the sequences contained in the insert participate in any way in pathogenic or harmful properties of the donor organism or vector.

8. Information on the genetically modified organism

8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification

8.2. Information on the DNA section that was inserted or deleted
- 8.2.1. Structure and size of the DNA insert, including information on each vector section inserted into the GMO, or on any carrier or foreign DNA remaining in the GMO,
- 8.2.2. In case of deletion of part of the heritable material, the size and function of each deleted nucleic acid segment
- 8.2.3. The location of the inserted heritable material in the cell
- 8.2.4. The copy number of the inserted heritable material
- 8.2.5. The stability of the inserted heritable material and the stability of its location
- 8.2.6. Methods of determining the data set forth in points 8.2.1 to 8.2.5.

8.3. Information on expression of the inserted heritable material
8.3.1. Methods used for characterization of the expression
8.3.2. Organs where the inserted genes are expressed
8.3.3. Rate and extent of expression, changes in expression in dependence on the life cycle
8.3.4. Stability of the expression
8.4. Expressed proteins
8.4.1. Activity of the expressed proteins
8.4.2. Description of identification and detection methods, giving their sensitivity, reliability and specificity
8.5. Information enabling unambiguous identification of the GMO
8.5.1. Description of the part of the altered DNA
8.5.2. Methods of detection and identification of the GMO, including methods of molecular biology
8.6. Stability of the GMO according to its heritable properties
8.7. Information on the way in which the GMO differs from the parental microorganism
means and rate of reproduction
dispersal in the environment
survivability
effects on the health of humans, animals and other organisms
other (specify)
8.8. Ability of the GMO to transfer genetic material to other organisms
8.9. Information on every potential harmful effect of the GMO, including its metabolic products, on the health of humans and animals caused by the genetic modification
pathogenicity/ infectivity
toxic or allergic effects
ability to colonize other organisms
other (specify)
8.10. Mechanism of interaction between the GMO and the target organism, if a target organism exists
8.11. Potential changes in the interactions of the GMO with nontarget organisms, following from the genetic modification
8.12. Potential interactions with nonliving components of the environment
8.13. The results of previous use of the GMO
8.13.1. Information on whether the GMO has been entered in the List for contained use pursuant to § 7 of the Act (if yes, state the date and number of the decision)
8.13.2. Information on whether the GMO has been entered in the List for introduction into the environment pursuant to § 8 of the Act (if yes, state the date and number of the decision)
8.13.3. Other information (e.g. registration / approval abroad, etc.)

9. Result of risk assessment of placing the GMO on the market - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on placing the GMO on the market in other countries

10.1. Information on whether the GMO has been registered/approved for placing on the market

in (where possible, state the number of designation of the registration)
10.1.1. Country
10.1.2. User / applicant / notifier (pursuant to the EC Directive)
10.1.3. Purpose of placing on the market
10.1.4. Period in time
10.2. Information on whether placing of the GMO on the market is planned in another country
10.2.1. Country
10.2.2. User / applicant / notifier (pursuant to the EC Directive)
10.2.3. Purpose
10.2.4. Date

11. Information related to the expected use of the GMO or product

11.1. Expected use of the GMO or product
11.2. Composition of the product
11.3. Target group of consumers (e.g. industry, agriculture, consumers in the public)
11.4. Differences between use of the GMO or product and use of similar modified organisms or products containing unmodified organisms
11.5. Description of ecosystems and agricultural areas in which the GMOs or products will be used, including estimation of the extent of use in the given area or in the given ecosystem
11.6. Information on each potential harmful effect of the GMO or product on human health caused by the genetic modification
11.7. Information on the safety of the GMO or product for the health of animals, especially in relation to any harmful effects caused by the genetic modification, if the GMO or product is to be used as part of feedingstuffs, veterinary medicinal substances, etc.
11.8. The mechanism of interaction between the GMO or product and the target organism, if a target organism exists
11.9. Potential changes in interactions of the GMO or product with nontarget organisms, following from the genetic modification
11.10. Potential interactions of the GMO or product with nonliving components of the environment
11.11. Information enabling unambiguous identification of the GMO or product
11.11.1. Description of the methods for determining the presence of the genetic modification, including the methods of taking and preparing samples
11.11.2. Information on the specificity and reliability of these methods
11.11.3. Description of the part of the altered nucleic acid permitting unambiguous identification of the GMO
11.12. Management of wastes that could contain the GMO or product
11.13. Proposed instructions for the consumer related to the use, transport and storage of the GMO or product, including waste management and any limitations on use
11.14. Safety instructions for the consumer
11.15. Proposed method of packaging and labelling the GMO and product
11.16. Estimate of the annual consumption / production / export / import after placing the GMO or product on the market in CR
11.17. Provision for, extent and manner of keeping records on use of the GMO or product after placing on the market
11.18. Provision for, extent and manner or monitoring the effects of the GMO or product on the

health of humans and animals, the environment and biological diversity (monitoring the GMO or product), if monitoring is to be carried out

11.19. Provision for, means of and frequency of taking and analyzing samples after placing the GMO or product on the market

11.20. Provision for, means of and frequency of informing the Ministry of the Environment of the use of the GMO or product afterplacing on the market, and on the results of monitoring, if required.

Annex No. 9 to the Decree 374/2000 Coll.

Sample application for entry in the List of genetically modified organisms and products registered for placing on the market in the Czech Republic for a genetically modified higher plants (GMHP), or for a product containing a GMHP

(Information denoted (+) must be accompanied by an original document or an officially authenticated copy)
All enclosed documents shall be denoted with the name of the user and the name (designation) of the genetically modified organism

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Date of submission

Summary information for the records

Application for entry in the List of genetically modified organisms registered for placing on the market in the Czech Republic	
Genetically modified organism	
Product	
Genetic modification	
Use of the GMHP or product	
Conclusions of the risk assessment	
Means of laboratory control of the presence of the genetic modification	
The user who applied for entry of the GMHP or product	
Duration of use	

1. The user submitting the application
(+) Excerpt from the Company Register (not more than 3 months old) or an officially authenticated copy of a small-business license, instruments of establishment or association

1.1. Name and surname / trade name / designation
1.2. State citizenship (for natural persons)
1.3. Legal form
1.4. Permanent address / registered office
1.5. Business Id. No.
1.6. Birth certificate number (for natural persons)
1.7. Tax Id. No. (if assigned)
1.8. Sphere of business (according to the instrument of association or entry in the Company Register)

1.9. Statutory body of the user (for legal persons)
1.9.1. Name, surname, title
1.9.2. Position

2. The professional consultant
(+) Excerpt from the Criminal Records not more than 3 months old
(+) Document of completed education and length of professional experience
2.1. Name, surname, title
2.2. Profession, and employer and position, as appropriate
2.3. Education
2.4. Professional courses
2.5. Experience to date
2.6. Permanent address
2.7. Contact address
2.8. Telephone
2.9. Fax
2.10. e-mail

3. Person responsible for supplying control samples after placing the GMHP or product on the market - the producer, distributor or importer, as appropriate
3.1. Identification information
3.2. Contact information

4. Commercial name of the GMHP or product, any other specifications of the GMHP or product, as appropriate

5. Placing the GMHP or product on the market
5.1. Use of the GMHP or product
5.2. Legal regulations governing the placing of the given GMHP or product on the market for the use specified in point 5.1.
5.3. Description of the individual stages in the placing on the market and the duration thereof, including the binding timetable for placing on the market
5.4. Expected amount of GMHP or product used in the individual stages, including specification of whether production in the territory of CR or import will be involved.

6. Information on (A) the recipient and (where appropriate) (B) the parental plant
(state separately for A and B, as appropriate)
6.1. Name
6.1.1. The order
6.1.2. The genus
6.1.3. The species
6.1.4. The subspecies
6.1.5. The variety / breeding line
6.1.6. The Czech name, Latin name
6.2. The origin (collection, collection number, supplier)
6.3. Reproduction

6.3.1. Modes of reproduction
6.3.2. Specific factor, affecting reproduction (if any)
6.3.3. Generation time
6.3.4. Sexual compatibility with other cultivated or wild species and distribution of these compatible species in CR

6.4. Survivability
6.4.1. Ability to form structures that enable survival or dormancy and the length of potential survival or dormancy
6.4.2. Specific factors enabling survivability, if any

6.5. Dissemination of the plants in the environment
6.5.1. Ways and extent of dissemination (decrease in the amount of pollen and seeds in dependence on distance from the source)
6.5.2. Specific factors affecting dissemination (if any)

6.6. Geographical distribution of the plant

6.7. If the plant is not cultivated in CR, a description of the natural habitat, including information on natural predators, parasites, competitors and symbionts

6.8. Other potentially significant interactions of the plant with other organisms in the ecosystem where it is usually cultivated, and elsewhere.

6.9. Effects on the health of humans, animals and other organisms
toxicity
allergenicity
other (specify)

7. Information on the genetic modification

7.1. The type of genetic modification
incorporation of foreign heritable material
deletion of part of the heritable material
combination of deletion and incorporation of heritable material
other (specify)

7.2. Description of the methods used in the genetic modification

7.3. Properties and origin of the vector used (if a vector was used in the genetic modification) (+ genetic map of the vector)

7.4. Information on each part of the section of the DNA that is to be inserted into the organism of the recipient (if the genetic modification includes insertion of heritable material)
7.4.1. Size
7.4.2. Position
7.4.3. Sequence
7.4.4. Origin (name of the donor organism)
7.4.5. Functional characteristics

8. Information on the genetically modified higher plant

8.1. Description and characteristics of the heritable properties and phenotypic traits, that were altered as a result of the genetic modification

8.2. Information on the DNA section that was inserted or deleted
8.2.1. Structure and size of the DNA insert, including information on each vector section inserted into the GMHP, or on any carrier or foreign DNA remaining in the GMHP,

8.2.2. In case of deletion of part of the heritable material, the size and function of the deleted nucleic acid segment
8.2.3. The location of the inserted heritable material in the plant cell (integrated in the chromosome, chloroplasts, mitochondria or in a non-integrated form)
8.2.4. The number of copies of the inserted heritable material
8.2.5. The stability of the inserted heritable material and the stability of its location
8.2.6. Methods of determining the data set forth in points 8.2.1 to 8.2.5.

8.3. Information on expression of the inserted heritable material
8.3.1. Methods used for characterization of the expression
8.3.2. Place where the inserted genes are expressed (e.g., roots, stem, leaves, pollen, etc.)
8.3.3. Changes in expression in dependence on the life cycle of the plant
8.3.4. Stability of the expression

8.4. Information permitting unambiguous identification of the GMHP
8.4.l. Description of the altered part of the DNA
8.4.2. Methods of detection and identification of the GMHP, including methods of molecular biology

8.5. Behaviour of the inserted genes
8.5.1. during hybridization with the same species
8.5.2. during hybridization with distant species

8.6. Information on how the GMHP differs from the recipient or parental organism
mode and rate of reproduction
dissemination in the environment
survivability
effects on the health of humans, animals and other organisms
effects on nontarget organisms
other (specify)

8.7. Phenotypical stability of the GMHP

8.8 Ability of the GMHP to transfer genetic material to other organisms

8.9. Information on any potential harmful effect of the GMHP on human health arising from the genetic modification

8.10. Information on the safety of the GMHP for animal health, particularly in relation to any harmful effects arising from the genetic modification, if the GMHP is to be used as feedingstuff

8.11. Mechanism of interaction between the genetically modified plant and the target organism, if a target organism exists

8.12. Potential changes in the interactions of the GMHP with nontarget organisms arising from the genetic modification

8.13. Potential interaction with nonliving components of the environment.

8.14. Information about release of the GMHP into the environment, during previous use of the GMHP, if appropriate
8.14.1. Information on whether the GMHP has entered in the List for introduction into the environment pursuant to § 8 of the Act (if yes, state the date and number of the decision)
8.14.2. Information on whether the GMO has released into the environment in other countries
8.14.3. Results of the release of the GMHP into the environment, especially in connection

with the effects of the GMHP on the health of humans and animals, the environment and biological diversity

8.14.4. Other previous use of the GMHP (approval / registration in other countries, etc.)

9. Result of risk assessment of release of the GMHP into the environment - classification in a risk category

(+) Risk assessment pursuant to § 4 of the Act

10. Information on placing the GMHP on the market in other countries

10.1. Information on whether the GMHP has been registered/approved for placing on the market in (where possible, state the number of designation of the registration)
- 10.1.1. Country
- 10.1.2. User / applicant / notifier (pursuant to the EC Directive)
- 10.1.3. Purpose of placing on the market
- 10.1.4. Period in time

10.2. Information on whether placing of the GMHP on the market is planned in another country
- 10.2.1. Country
- 10.2.2. User / applicant / notifier (pursuant to the EC Directive)
- 10.2.3. Purpose
- 10.2.4. Date

11. Information related to the expected use of the GMHP or product

11.1. Expected use of the GMHP or product

11.2. Composition of the product

11.3. Target group of consumers (e.g. industry, agriculture, consumers in the public)

11.4. Difference between use of the GMHP or product and use of similar unmodified organisms or products containing unmodified plants

11.5. Description of ecosystems and agricultural areas in which the GMHPs or products will be cultivated or used, including estimation of the extent of cultivation or use in the given area or in the given ecosystem

11.6. Information on any potential harmful effect of the GMHP or product on human health caused by the genetic modification

11.7. Information on the safety of the GMHP or product for the health of animals, especially in relation to any harmful effects caused by the genetic modification, if the GMHP or product is to be used as feedingstuff

11.8. The mechanism of interaction between the GMHP or product and the target organism, if a target organism exists

11.9. Potential changes in interactions of the GMHP or product with nontarget organisms, following from the genetic modification

11.10. Potential interactions of the GMHP or product with nonliving components of the environment.

11.11. Information enabling unambiguous identification of the GMHP or product
- 11.11.1. Description of the methods for determining the presence of the genetic modification, including the methods of taking and preparing samples
- 11.11.2. Information on the specificity and reliability of these methods
- 11.11.3. Description of the part of the altered nucleic acid permitting unambiguous

identification of the GMHP

11.12. Management of wastes that could contain the GMHP or product

11.13. Proposed instructions for the consumer related to the use, transport and storage of the GMHP or product, including waste management and any limitations on use

11.14. Safety instructions for the consumer

11.15. Proposed method of packaging and labelling the GMHP and product

11.16. Estimate of the annual consumption / production / export / import after placing the GMHP or product on the market in CR

11.17. Provision for, extent and manner of keeping records on use of the GMHP or product after placing it on the market

11.18. Provision for, extent and manner or monitoring the effects of the GMHP or product on the health of humans and animals, the environment and biological diversity (monitoring the GMHP or product), if monitoring is to be carried out

11.19. Provision for, means of and frequency of taking and analyzing samples after placing the GMHP or product on the market

11.20. Provision for, means of and frequency of informing the Ministry of the Environment of the use of the GMHP or product after placing it on the market, and on the results of monitoring, if required.